



BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Reporting of Conflicts of Interest by Authors of Primary Studies on Health Policy and Systems Research: a Cross-sectional Survey

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-032425
Article Type:	Research
Date Submitted by the Author:	27-Jun-2019
Complete List of Authors:	Hakoum, Maram; American University of Beirut, Clinical Research Institute Bou-Karroum, Lama ; American University of Beirut Al-Gibbawi, Mounir; American University of Beirut Faculty of Medicine Khamis, Assem; American University of Beirut, Internal Medicine Raslan, Abdul Sattar ; American University of Beirut Badour, Sanaa ; American University of Beirut Medical Center Agarwal, Arnav; University of Toronto, Faculty of Medicine Alturki, Fadel ; American University of Beirut Guyatt, Gordon; McMaster University, Clinical Epidemiology and Biostatistics El-Jardali, Fadi; Department of Health Management and Policy, Faculty of Health Sciences, American University of Beirut, Beirut, Lebanon, and 2Sch, Akl, Elie; American University of Beirut,
Keywords:	conflict of interest, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, health systems research

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Manuscript Title: Reporting of Conflicts of Interest by Authors of Primary Studies on Health Policy and Systems Research: a Cross-sectional Survey

Names and affiliations of all contributing authors:

Maram B. Hakoum¹ maram.hakoum@gmail.com, Lama Bou-Karroum² lb25@aub.edu.lb, Mounir Al-Gibbawi³ mounir.algibbawi@gmail.com, Assem M. Khamis¹ amk88@mail.aub.edu, Abdul Sattar Raslan³ anr06@mail.aub.edu, Sanaa Badour⁴ badoursa@hotmail.com, Arnav Agarwal^{5,6} arnav.agarwal@mail.utoronto.ca, Fadel Alturki³ fma46@mail.aub.edu, Gordon Guyatt⁶ guyatt@mcmaster.ca, Fadi El-Jardali^{6,7,8} fe08@aub.edu.lb, Elie A. Akl^{1,4,6} ea32@aub.edu.lb

¹ Clinical Research Institute, American University of Beirut Medical Center, Beirut, Lebanon

²Center for Systematic Reviews for Health Policy and Systems Research, American University of Beirut, Beirut, Lebanon

³ Faculty of Medicine, American University of Beirut, Beirut, Lebanon

⁴Department of Internal Medicine, American University of Beirut Medical Center, Lebanon

⁵Department of Medicine, University of Toronto, Toronto, Ontario, Canada

⁶Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada

⁷Knowledge to Policy (K2P) Center, Faculty of Health Sciences, American University of Beirut, Lebanon

⁸Department of Health Management and Policy, Faculty of Health Sciences, American University of Beirut, Lebanon

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Corresponding author:

Elie A. Akl, MD, MPH, PhD

Department of Internal Medicine

American University of Beirut Medical Center

P.O. Box: 11-0236

Riad-El-Solh Beirut 1107 2020

For peer review only

Abstract

Objectives: The objective of this study was to assess the frequency and types of conflict of interest (COI) disclosed by authors of primary studies of Health Policy and Systems Research (HPSR).

Design: We conducted a cross sectional survey using standard methodology for study selection and data extraction. We conducted descriptive analyses.

Setting: We did not restrict to any specific setting.

Participants: We included primary studies of HPSR published in English in 2016.

Outcome measures: Reported COI disclosures.

Results: We included 200 eligible primary studies of which 132 (66%) included COI disclosure statements of authors. Of the 132 studies, 14% studies had at least one author reporting at least one type of COI and the most frequently reported type was individual financial COI (n=15, 11%). None of the authors reported individual intellectual COIs or personal COIs. Financial and individual COIs were reported more frequently compared with non-financial and institutional COIs.

Conclusion: COI disclosure statements are less frequently included in HPSR primary studies as compared to the clinical field. Few HPSR primary studies included authors reporting any type of COI, in particular non-financial or institutional COIs. HPSR journals should consider strengthening their COI disclosure policies, and their implementation.

Keywords: conflict of interest, health policy, health systems

Strengths and limitations of this study
--

- This is the first study to assess the frequency and types of COI disclosed by authors of primary studies of HPSR.
- The study used a rigorous methodology that included a search strategy specific to health policy journals and duplicate study selection and data abstraction processes.
- We used a comprehensive framework for the classification of COI validated in previous studies.
- The study focused on reported COI, thus these statements depend on journals COI policy requirements, and whether authors' disclosures are accurate or complete remains uncertain.

Background

Evidence-informed health policymaking aims to ensure that policymaking is well-informed by the best available evidence¹. Evidence from Health Policy and Systems Research (HPSR) can inform health system policy decisions including who delivers health services and where, and how these services are financed and organized^{2,3}. Policymakers are increasingly recognizing the importance of the use of research evidence in improving health, reducing health inequities and contributing to economic development^{4,5}.

Conflict of interest (COI) of researchers may influence the conduct and reporting of HPSR. COI is defined as “a financial or intellectual relationship that may impact an individual’s ability to approach a scientific question with an open mind”⁶. One study assessing the frequency and influence of financial COI on economic analyses in oncology found that the studies disclosing financial COI directly or indirectly consistently supported the sponsor’s product⁷. Forsyth et al. found that opinion articles skeptical of the use of systematic reviews for policy-making were more likely to have industry ties than articles supportive of their use⁸.

Reporting of COI in HPSR is important given its potential influence on public policy and decision-making. We previously assessed the reporting of COI in HSPR systematic reviews⁹. We found that 20% of those reviews did not include a COI disclosure statement, and only 15% of disclosure statements reported the existence of any COI. The reporting of COI in primary studies is important for both policy makers, relying on their

findings for decision making, as well for authors of systematic reviews assessing the potential bias associated with the COI of study investigators ¹⁰. Therefore, this study aims to assess the types and frequency of COI disclosed by authors of primary studies of HPSR.

Methods

Design overview and definitions

We conducted a cross-sectional survey using standard methodology for study selection and data extraction. We defined COI disclosure as the reporting of whether a COI exists or not. We classified the types of disclosed COIs as shown in figure 1 and detailed in S1 appendix. Our classification of COIs relies on a framework informed by a literature review, the findings of recent studies assessing COIs reported by authors of clinical systematic reviews, HPSR systematic reviews and randomized controlled trials ^{9 11 12} and the International Committee of Medical Journal Editors (ICMJE) COI disclosure form. We used the word “loogly” to label “any additional statement in the COI disclosure that attempts to downplay a disclosed relationship by suggesting that it is unrelated to COI” (e.g., ‘this relationship did not influence the content of the manuscript’) ¹¹.

Insert Figure 1 here

Figure 1: Classification of conflicts of interest

Eligibility criteria

We included articles meeting the following eligibility criteria:

- Type of study: primary studies (e.g., randomized controlled trials, cohort studies, qualitative studies). We excluded systematic and literature reviews, case studies, technical reports, conference reports, proceedings, editorials and opinion pieces;
- Type of field: health policy and systems research; we used the taxonomy of health systems topics used to code Health Systems Evidence (HSE) database of McMaster Health Forum to assess eligibility: governance, financial, delivery arrangements, and implementation strategies^{13 14};
- Articles published in English in 2016.

Search strategy

We searched for papers published in peer-reviewed health policy and services journals. We ran the search in the Web of Science database limiting to “Health Policy and Services” journal category, “article” document type, English language and to the year 2016. S2 appendix presents the detailed search strategy.

Selection process

We drew a random sample of 200 papers from the set of citations retrieved by the search to undergo the selection process using an online random sequence generator (www.random.org/sequences). Citations were exported to EndNote™ X7.5 software (Thomson Reuters, Philadelphia, PA, USA). Reviewers completed calibration exercises before starting the selection process. Two reviewers screened title and abstracts for eligibility in duplicate and independently using EndNote. We retrieved the full text of citations judged as potentially eligible by at least one of the two reviewers. The two

reviewers screened the full texts in duplicate and independently. The reviewers resolved their disagreements by discussion, and consulted a third reviewer when consensus could not be reached. We used a standardized and pilot tested full text screening form. We recorded reasons for exclusion and summarized the selection process results in a PRISMA study flow diagram ¹⁵.

Data extraction process

We developed and pilot-tested a standardized data extraction form with detailed instructions. Two teams of eight reviewers completed calibration exercises and extracted data in duplicate and independently. Reviewers extracted study data using Research Electronic Data Capture (REDCap) tool, a secure, web-based application designed to support data capture for research studies ¹⁶. The reviewers compared results and resolved disagreements through discussion, or with the help of a third person when consensus could not be reached.

Extracted data

We extracted the following general characteristics of each article:

- Number of authors;
- Reported affiliation(s) of first and last author (private or public academic institution, government, not-for-profit organization, private-for-profit, intergovernmental);
- Country of affiliation of the first author and its classification (as per World Bank list of economies issued in September 2016);

- Health systems arrangement of the paper (governance, financial, delivery arrangements, and implementation strategies).

We extracted the following characteristics of the reported COI disclosures (as defined above):

- Whether authors reported COI or not;
- Form in which COI disclosures were provided (a narrative statement, an online document, available upon request);
- Number of authors per paper that report any type of COI;
- Number of authors per paper that report each specific type of COI, and when applicable, the different subtypes of COI;
- Whether the paper reports relevant characteristics of the COI (source, monetary value, duration);
- Whether individuals other than the authors provided COI disclosures (e.g. editors, peer-reviewers, external writers, others).

Data analysis

For eligible articles, we conducted descriptive analyses, focusing on the reported COI disclosures. For continuous variables, we present summary data as medians and quartiles since the application of the Kolmogorov–Smirnov (K–S) test did not demonstrate normality. We presented the results for categorical variables as frequencies and percentages, and analyzed them using the Chi-square test or, if the expected event number proved less than 5, the Fisher’s Exact test. We considered a p-value of < 0.05 as

statistically significant. We performed the analysis using SPSS, version 21.0 for Windows (SPSS INC., Chicago, IL, USA).

Results

Out the 2648 citations identified, we included 200 eligible primary studies that were published in 55 “Health Policy & Services” journals. Figure 2 shows the study flow diagram.

Insert Figure 2

Figure 2: Study flow diagram

General characteristics of the included primary studies

Table 1 presents the general characteristics of the included primary studies. The median number of authors per study was four. Most studies were conducted by authors affiliated with institutions located in high-income countries (92%) and addressed the topic of delivery arrangements (72%). Most first authors and last authors were affiliated with public academic institutions (68% and 65% respectively).

Table 1: General characteristics of the included primary studies (N=200)

	Overall
	N (%)
Number of authors; Median (Interquartile range)	4 (3 – 6)
Classification of the country of the institution to which the first author is affiliated:	

<i>High income</i>	183 (92)
<i>Upper middle income</i>	10 (5)
<i>Lower middle income</i>	4 (2)
<i>Low income</i>	3 (2)
Affiliation of first author *	
<i>Public academic institution</i>	135 (68)
<i>Private academic institution</i>	46 (23)
<i>Government</i>	18 (9)
<i>Not-for-profit organization</i>	23 (12)
<i>Private-for-profit</i>	2 (1)
<i>Intergovernmental</i>	1 (1)
Affiliation of last author *	
<i>Public academic institution</i>	129 (65)
<i>Private academic institution</i>	51 (26)
<i>Government</i>	21 (11)
<i>Not-for-profit organization</i>	20 (10)
<i>Private-for-profit</i>	3 (2)
<i>Intergovernmental</i>	0 (0)
Type of Health Systems Arrangement *	
<i>Delivery arrangement</i>	143 (72)
<i>Implementation strategies</i>	25 (13)
<i>Governance arrangement</i>	23 (12)
<i>Financial arrangement</i>	67 (34)

* Studies may have more than one option that applies.

Characteristics of the reported COI disclosures

Of the primary studies, 66% (132/200) included COI disclosure statements of authors. All but one study provided COI disclosures narratively in the main document; the single study provided them in an online form that was not accessible. None of the included studies reported COI by individuals other than the authors (e.g. editors or peer-reviewers).

Table 2 presents the reporting of the different types of COI in the 132 studies that provided COI disclosure statements. Of these 132 studies, 19 (14%) had at least one author reporting at least one type of COI. The most frequently reported type was individual financial COI (n=15, 11%), with the median percentage of authors reporting that COI being 25% (out of the 132 studies with at least one author reporting that type of COI). None of the authors reported individual intellectual COIs or personal COIs. Of the 132 primary studies that provided COI disclosure statements, more had at least one author reporting financial COIs compared to non-financial COIs (n=16; 12% versus n=3; 2%; p-value=0.04). More studies had at least one author reporting individual COIs compared to institutional COIs (n=15; 11% versus n=5; 4%; p-value=0.01).

Table 2: Reporting by primary study authors of the different types of conflict of interest (COI) (N=132)

	Studies with at least one author reporting a specific type of COI *; n (%)	Distribution of the percentage of authors per study reporting that type of COI §; Median (Interquartile range)
--	---	---

At least one type	19 (14)	25 (17 – 50)
Individual financial (direct benefit)	15 (11)	25 (15 – 50)
Individual financial (benefit through professional status)	0 (0)	N/A
Individual intellectual	0 (0)	N/A
Individual personal	0 (0)	N/A
Institutional financial	2 (2)	^a
Institutional intellectual	3 (2)	^b
Institutional cultural	0 (0)	N/A
“Other types” [§]	4 (3)	30 (18 – 85)
Provided a “loogly statement”	3 (2)	^c

* One study can have authors reporting more than one type of COI.

§ Calculated using the number of papers with at least one author reporting the specific type of COI (i.e., papers counted in the preceding column) as the denominator.

§ “Other types” of COIs included: ‘implementing national clinical audit’ (n=1), ‘non-compensated affiliations’ (n=1), ‘attended meetings’ (n=1), and relationship with a publishing entity (n=1). We consider these as individual and non-financial types of COI.

^a Authors of only 2 studies reported institutional financial COI, with the percentages being 20% and 100%.

^b Authors of only 3 studies reported institutional intellectual COI, with the percentages being 20%, 25%, and 33%.

^c Authors of only 3 studies provided a “loogly statement”, with the percentages being 10%, 25% and 100%.

N/A=Not applicable

Individual financial COI: Table 3 presents the reporting of the different subtypes of individual financial COI in the 15 primary studies with at least one author reporting individual financial COI. The two most frequently reported subtypes were ‘personal fees’

(n=9; 60%) and ‘grant’ (n=6, 40%). The median percentages of authors reporting these two subtypes were 20% and 18% respectively.

Table 3: Reporting of primary study authors of different subtypes of individual financial conflict of interest (COI) (N=15)

	Studies with at least one author reporting the subtype of individual financial COI *; n (%)	Distributions of the percentage of authors per study reporting that subtype of COI §; Median (Interquartile range)
Grant	6 (40)	18 (9 – 27)
Employment	2 (13)	^a
Personal fees (other than employment)	9 (60)	20 (12 – 38)
Non-monetary support	1 (7)	^b
Study supplies/services	0 (0)	N/A
Patent(s)	0 (0)	N/A
Stocks, bonds, stock options, other securities	3 (20)	^c
“Other subtypes”	0 (0)	N/A

* One study can have authors reporting more than one type of COI.

§ Calculated using the number of papers with at least one author reporting the specific type of COI (i.e., papers counted in the preceding column) as the denominator.

^a Authors of only 2 studies reported “Employment”, with the percentages being 50% and 100%.

^b Authors of only 1 study reported “Non-monetary support”, with the percentage being 17%.

^c Authors of only 3 studies reported “Stocks, bonds, stock options, other securities”, with the percentages being 20%, 25% and 33%.

N/A=Not applicable

Of the 15 studies with at least one author reporting individual financial COI, 14 reported the source of financial COI. Only two of these 14 studies specified the relationship of the source to the field under study; in both cases, the sources produced a product not the subject of the study but under the same field. Only one of the 15 studies reported on the timing of the conflicted relationship relative to the conduct of the study; in that case, the relationship occurred during the conduct of the study. None of the studies reported on the monetary value of the financial COI.

Discussion

Summary of findings

In summary, 66% of 200 HPSR primary studies included COI disclosure statements of authors, with only one using an online disclosure form. Of these studies, 14% had at least one author reporting at least one type of COI. Most frequently, authors reported individual financial COI. Very few studies reported non-financial or institutional COIs. The two most frequently reported subtypes of individual financial COI were 'personal fees' and 'grant'. None of the studies reported on the monetary value of the financial COI, or provided disclosure by individuals other than the authors such as editors or reviewers.

Strengths and limitations

This is the first study to assess the frequency and types of COI disclosed by authors of primary studies of HPSR. We have used a rigorous methodology that included a search

strategy specific to health policy journals and duplicate study selection and data abstraction processes. We used a comprehensive framework for the classification of COI validated in previous studies. Our study focused on reported COI, thus these statements depend on journals COI policy requirements, and whether authors' disclosures are accurate or complete remains uncertain.

Comparison to other studies

Our findings, in relation to similar studies, demonstrate that COI disclosure statements are less frequently included in HPSR primary studies (66%) compared to HPSR systematic reviews (80%), clinical randomized controlled trials (94%), and clinical systematic reviews (97%) (figure 3) ^{9 11 12}. Factors that may be contributing to these differences include the less rigorous COI policies in HPSR journals compared to Core Clinical journals, and potentially a less strict implementation: 93% of HPSR journals have a COI disclosure policy compared to 99% for Core Clinical journals ^{17 18}.

The percentage of authors reporting any type of COI in HPSR primary studies (14%) was comparable to that of HPSR systematic reviews (15%). However, that percentage as much lower compared to that of clinical systematic reviews (41%) and clinical trials (57%) ^{9 11 12}. One explanation could be that HPSR authors may have less COIs than authors in the clinical field.

Reporting of financial COI was higher than non-financial COI in HPSR primary studies. This is consistent with the findings of previous studies that focused on COI reporting in

HPSR systematic reviews, clinical systematic reviews, and randomized controlled trials⁹
^{11 12}. Although this might reflect how frequently these types of COI exist, it might also be
that authors are less aware of the concept of non-financial COI, or of what exactly
qualifies as a non-financial COI. Another explanation could be related to the extent of use
of standard COI disclosure forms: we found that only one study used a standardized form
to report COI, compared to 12% in clinical trials¹².

Insert Figure 3 here

Figure 3: chart comparing the reporting of financial and non-financial COI in different
types of publications. The denominator for the reporting of the different types of COI is
the number of studies that included a COI disclosure statement.

Implications for practice and research

Findings of this study should motivate HPSR journals to strengthen their COI disclosure
policies, and the implementation of existing policies. One approach to help authors better
recognize and disclose their COIs would be to develop a standardized COI disclosure
form similar to that of the ICMJE but more specific to health policy and systems
research. Journals publishing HPSR should also consider collecting and publishing the
COIs of editors and peer-reviewers. Future research should investigate the reasons behind
the higher reporting of financial COI compared with non-financial COI in HPSR primary
studies. Investigate of the accuracy and completeness of reporting of COI may also
provide insight into the low rates of disclosed COI.

Contributions: MBH, LBK, FEJ, GG, and EAA conceived and designed the study. MBH coordinated the study throughout. EAA had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. MBH and LBK ran the search and study selection processes. MBH, LBK, MAG, AK, ASR, SB, AA, and FA extracted the data. MBH, LBK, and EAA analyzed and interpreted the data. MBH and LBK wrote the first draft of the manuscript with EAA. All authors critically revised the manuscript and approved the final version. The lead author EAA affirms that this manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Funding: This work was supported by the American University of Beirut Faculty of Medicine’s Medical Practice Plan (MPP) funds.

Acknowledgements: None

Competing interests: None declared.

Ethics approval: The study involves no human subjects and requires no ethical approval.

Patient and Public Involvement: It was not appropriate or possible to involve patients or the public in this work.

Data sharing statement: All data relevant to the study are included in the article or uploaded as supplementary information.

References

1. Oxman AD, Lavis JN, Lewin S, et al. SUPPORT Tools for evidence-informed health Policymaking (STP) 1: What is evidence-informed policymaking? *Health research policy and systems* 2009;7 Suppl 1:S1. doi: 10.1186/1478-4505-7-s1-s1 [published Online First: 2009/12/19]
2. Gilson L, Hanson K, Sheikh K, et al. Building the Field of Health Policy and Systems Research: Social Science Matters. *PLoS Medicine* 2011;8(8):e1001079. doi: 10.1371/journal.pmed.1001079
3. Koon AD, Rao KD, Tran NT, et al. Embedding health policy and systems research into decision-making processes in low- and middle-income countries. *Health research policy and systems* 2013;11(1):30. doi: 10.1186/1478-4505-11-30
4. Lavis JN, Posada FB, Haines A, et al. Use of research to inform public policymaking. *The Lancet*;364(9445):1615-21. doi: 10.1016/S0140-6736(04)17317-0
5. El-Jardali F, Lavis JN, Ataya N, et al. Use of health systems evidence by policymakers in eastern mediterranean countries: views, practices, and contextual influences. *BMC Health Services Research* 2012;12(1):200. doi: 10.1186/1472-6963-12-200
6. Schunemann HJ, Osborne M, Moss J, et al. An official American Thoracic Society Policy statement: managing conflict of interest in professional societies. *American journal of respiratory and critical care medicine* 2009;180(6):564-80. doi: 10.1164/rccm.200901-0126ST
7. Jang S, Chae YK, Majhail NS. Financial Conflicts of Interest in Economic Analyses in Oncology. *American Journal of Clinical Oncology* 2011;34(5):524-28. doi: 10.1097/COC.0b013e3181f4799b
8. Forsyth SR, Odierna DH, Krauth D, et al. Conflicts of interest and critiques of the use of systematic reviews in policymaking: an analysis of opinion articles. *Systematic reviews* 2014;3:122. doi: 10.1186/2046-4053-3-122 [published Online First: 2014/11/25]
9. Bou-Karroum L, Hakoum MB, Hammoud MZ, et al. Reporting of Financial and Non-financial Conflicts of Interest in Systematic Reviews on Health Policy and Systems Research: A Cross Sectional Survey. *International journal of health policy and management* 2018;7(8):711-17. doi: 10.15171/ijhpm.2017.146
10. Elia N, von Elm E, Chatagner A, et al. How do authors of systematic reviews deal with research malpractice and misconduct in original studies? A cross-sectional analysis of systematic reviews and survey of their authors. *BMJ Open* 2016;6(3):e010442. doi: 10.1136/bmjopen-2015-010442
11. Hakoum MB, Anouti S, Al-Gibbawi M, et al. Reporting of financial and non-financial conflicts of interest by authors of systematic reviews: a methodological survey. *BMJ Open* 2016;6(8):e011997. doi: 10.1136/bmjopen-2016-011997
12. Hakoum MB, Jouni N, Abou-Jaoude EA, et al. Authors of Clinical Trials Reported Individual and Financial Conflicts of Interest More Frequently than Institutional and non-financial Ones: a Methodological Survey. *J Clin Epidemiol* 2017 doi: 10.1016/j.jclinepi.2017.04.002
13. About HSE. : Health Systems Evidence; [Available from: <https://www.healthsystemsevidence.org/about>. 2016.

1
2
3 14. Lavis JN, Wilson MG, Moat KA, et al. Developing and refining the methods for a
4 'one-stop shop' for research evidence about health systems. *Health research policy*
5 *and systems* 2015;13:10. doi: 10.1186/1478-4505-13-10 [published Online First:
6 2015/05/15]
7
8 15. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic
9 reviews and meta-analyses: the PRISMA statement. *PLoS Med*
10 2009;6(7):e1000097. doi: 10.1371/journal.pmed.1000097 [published Online First:
11 2009/07/22]
12
13 16. Harris PA, Taylor R, Thielke R, et al. Research Electronic Data Capture (REDCap) -
14 A metadata-driven methodology and workflow process for providing translational
15 research informatics support. *Journal of biomedical informatics* 2009;42(2):377-
16 81. doi: 10.1016/j.jbi.2008.08.010
17
18 17. Khamis AM, Hakoum MB, Bou-Karroum L, et al. Requirements of health policy and
19 services journals for authors to disclose financial and non-financial conflicts of
20 interest: a cross-sectional study. *Health research policy and systems*
21 2017;15(1):80. doi: 10.1186/s12961-017-0244-2
22
23 18. Shawwa K, Kallas R, Koujanian S, et al. Requirements of Clinical Journals for
24 Authors' Disclosure of Financial and Non-Financial Conflicts of Interest: A Cross
25 Sectional Study. *PLoS ONE* 2016;11(3):e0152301. doi:
26 10.1371/journal.pone.0152301
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

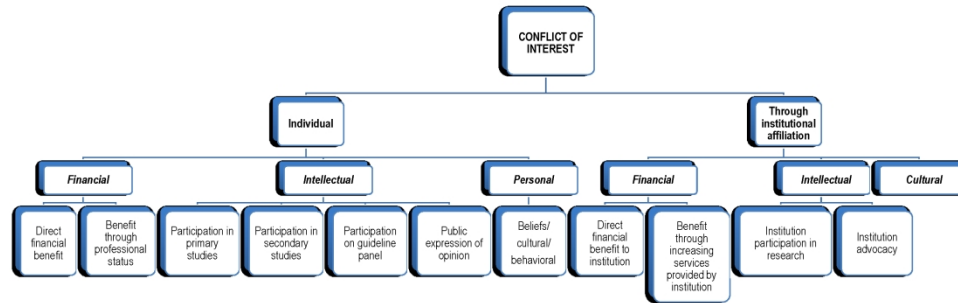


Figure 1: Classification of conflicts of interest

240x130mm (300 x 300 DPI)

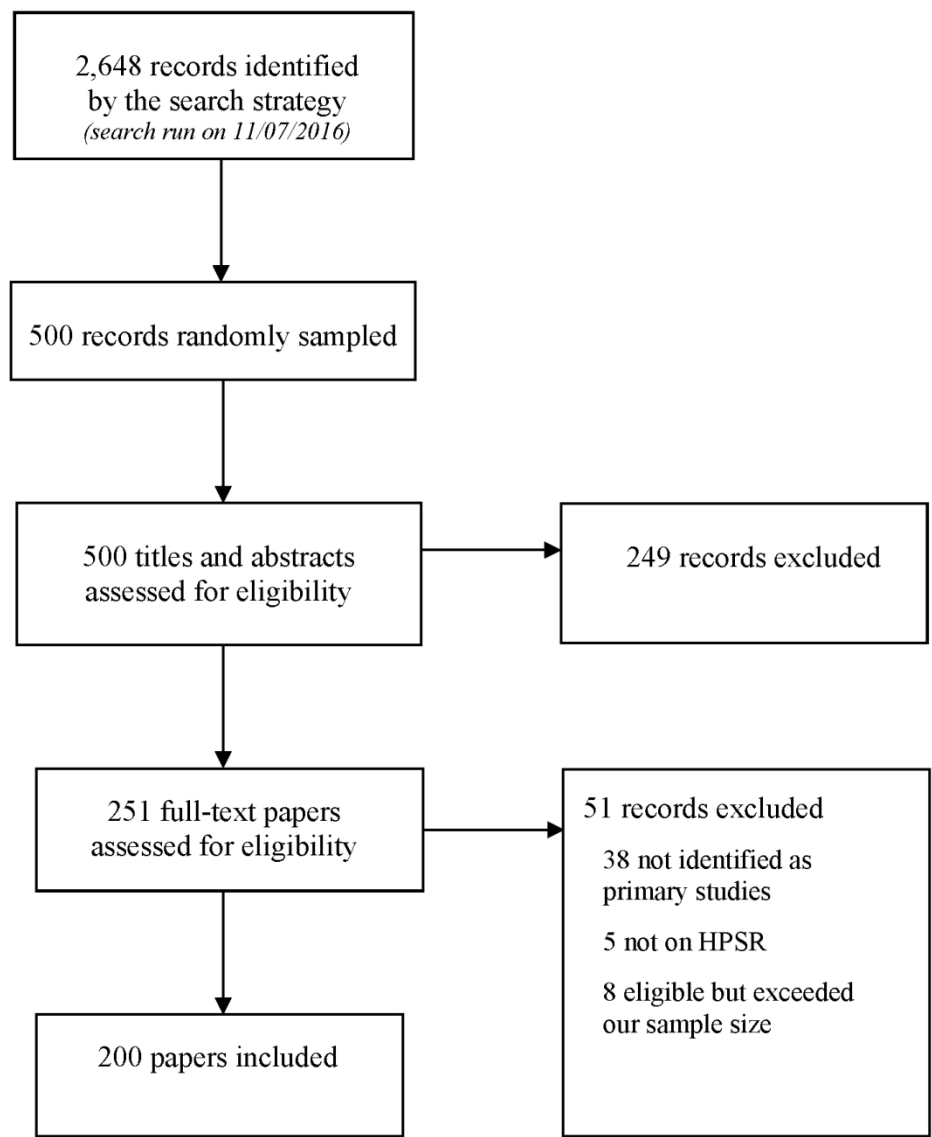


Figure 2: Study flow diagram
130x155mm (300 x 300 DPI)

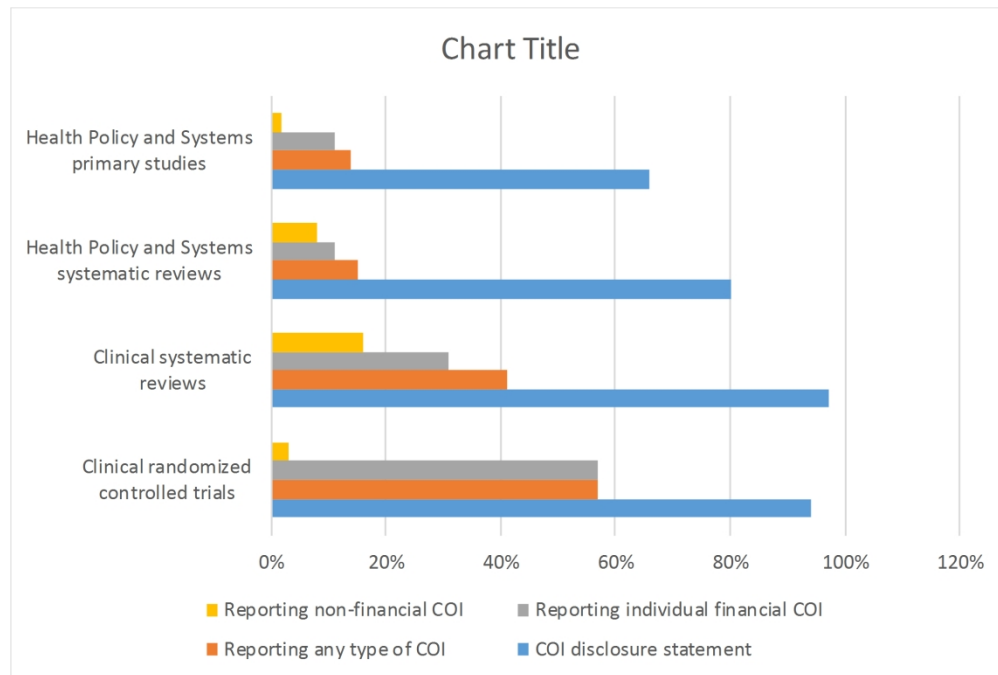


Figure 3: chart comparing the reporting of financial and non-financial COI in different types of publications. The denominator for the reporting of the different types of COI is the number of studies that included a COI disclosure statement.

198x133mm (300 x 300 DPI)

S1 Appendix: Classification of conflicts of interest

Conflicts of interest can be individual or exist through institutional affiliations:

- Individual COIs. Types of individual COI include financial, intellectual and personal COIs.
- Types of institutional COI include financial, intellectual and cultural COIs.

Part 1: Classification of individual financial COI

Part 1a: Individual financial COI with direct financial benefit

<p>Definition:</p> <p>Individual financial COI with direct financial benefit arises from any payment, research funding, consultancy, advisory board membership, and the like from the manufacturer of a drug or device or service under consideration. This type of COI may involve the individuals themselves, their families or a business they own. Typically, a timeframe of three to five years is considered for these COIs.</p>	
Grant	<i>There could be a differentiation whether the grant is going to the investigator or to his/her institution. Types: grant; salary for research; contract; fellowship; unrestricted educational funding; peer-reviewed grant funding</i>
Employment	<i>Types: former employment; current employment; stipend; salary</i>
Personal fees (other than employment)	<i>Types: honoraria, royalties, fees for consulting, lectures, speakers' bureaus, expert testimony, presentations, editorial work, manuscript preparation, trial involvement. management, educational support, production of books, article research, scientific meetings, entertainment, gift, charitable contribution, other affiliations (e.g. advisory board, steering committee membership, supported by another party for holding a chair at one's institution)</i>

Non-monetary support	<i>Types: travel paid; writing assistance; administrative support; food and beverage</i>
Study supplies/services	
Patent(s)	
Stocks, bonds, stock options, other securities (e.g. equity)	
Other forms	

Part 1b: Individual financial COI with benefit through professional status

Definition:
Individual financial COI with benefit through professional status arises when an individual is "engaged in a specified activity as one's main paid occupation" or "a member of a professional group of individuals".

e.g. an author that is a dietician conducts a study looking at advice vs. no advice from a dietician; an author that provides colonoscopy services; an author that works at a warfarin clinic

Part 2: Classification of individual intellectual COI

Definition:
Individual intellectual COI arises when an individual participates in scholarly activities related to the issue under consideration, or when an individual has taken a position or has an opinion and expresses it in a statement publicly. Such activities may result in an emotional attachment to a particular interpretation of evidence or position regarding optimal course of action.

Participation in primary studies	<i>e.g. randomized controlled trials; case-control studies, observational studies, qualitative studies</i>
Participation in secondary studies	<i>e.g. systematic reviews</i>
Participation on guideline panel	<i>e.g. Chair of American Heart Association Get With The Guidelines Steering Committee</i>

Public expression of opinion	<i>e.g. textbook; review article; editorial; presentation</i>
------------------------------	---

Part 3: Classification of individual personal COI

Definition: when an individual has personal opinions or conditions that concern one's private life, relationships, and emotions rather than one's career or public life.	
Beliefs (religious, political, philosophical)	<i>e.g. an author against organ donation or abortion attributed to personal religious beliefs</i>
Personal characteristics (gender, age, race, physical/psychiatric condition, sexual orientation)	<i>e.g. an author with a physical disability conducting a study on the benefit of physical rehabilitation</i>

Part 4: Classification of institutional financial COI

Part 4a: Institutional financial COI with direct financial benefit to the institution

Definition: Institutional financial COI arises when an institution, to which an individual belongs, has a relationship with the manufacturer of a drug or device or service under consideration. Such institutions include academic medical centers and professional societies.	
Seeking and receiving gifts, endowments, or grants from companies, for example, a gift of an endowed university chair	<i>Types: grants for research/fellowship/salary support; merit awards; endowments; patent funds; educational fees; funds for author activities (speaker fee, consultancy, honoraria, board membership, testimony, writing); funds for drug/equipment supplies</i>
Conduct of research within the institution that relates to the issue under consideration and could affect the value of the institution's patents or its equity positions or options in biotechnology, pharmaceutical, or medical device companies	
Senior officials who act on behalf of the institution have personal financial interests related to the issue under consideration	

Part 4b: Institutional financial COI with benefit through increasing services provided by the institution

Definition:

when an institution employs professionals who advocate for clinical services related to the issue under consideration but don't provide those services themselves.

Part 5: Classification of institutional intellectual COI

Definition:

Institutional intellectual COI arises when an institution/organization, to which an individual belongs, focuses or funds research on a specific topic, or arises when an individual (paid employee or unpaid member) belongs to an institution/organization that clearly advocates for the issue under consideration.

Institution participation in research

e.g. an author works at a hospital which is enrolling participants in a trial on a certain topic; an author is a member of an organization that has a research focus on a certain topic

Institution advocacy when the institution:

1. *is an advocacy group that clearly advocates for the issue under consideration*
2. *has advocacy related to the issue under consideration as part of its mission, objectives, work, or stated position (i.e. position statement, editorial, blog, amicus brief, or legislature or legal testimony)*
3. *shows "public support for or recommendation of a particular cause or policy"*
4. *has senior officials who act on its behalf and have COI related to the issue under consideration*

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Part 6: Classification of institutional cultural COI

Definition:
Institutional cultural COI arises when an individual (paid employee or unpaid member) belongs to an institution/organization that has a specific cultural identity (e.g. catholic university).

For peer review only

S2 Appendix: Search strategy

Web of Science search strategy for health policy and services papers

1. Advanced search for “WC=(Health Policy & Services)”
2. Limit to “English”
3. Refine document types to “article”
4. Limit time span to: “01/01/2016 to present”
5. Select Social Sciences Citation Index

BMJ Open

Reporting of Conflicts of Interest by Authors of Primary Studies on Health Policy and Systems Research: a Cross-sectional Survey

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-032425.R1
Article Type:	Original research
Date Submitted by the Author:	13-Oct-2019
Complete List of Authors:	Hakoum, Maram; American University of Beirut, Clinical Research Institute Bou-Karroum, Lama ; American University of Beirut Al-Gibbawi, Mounir; American University of Beirut Faculty of Medicine Khamis, Assem; American University of Beirut, Internal Medicine Raslan, Abdul Sattar ; American University of Beirut Badour, Sanaa ; American University of Beirut Medical Center Agarwal, Arnav; University of Toronto, Faculty of Medicine Alturki, Fadel ; American University of Beirut Guyatt, Gordon; McMaster University, Clinical Epidemiology and Biostatistics El-Jardali, Fadi; Department of Health Management and Policy, Faculty of Health Sciences, American University of Beirut, Beirut, Lebanon, and 2Sch, Akl, Elie; American University of Beirut,
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health policy, Public health
Keywords:	conflict of interest, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, health systems research

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Manuscript Title: Reporting of Conflicts of Interest by Authors of Primary Studies on Health Policy and Systems Research: a Cross-sectional Survey

Names and affiliations of all contributing authors:

Maram B. Hakoum¹ maram.hakoum@gmail.com, Lama Bou-Karroum² lb25@aub.edu.lb,

Mounir Al-Gibbawi³ mounir.algibbawi@gmail.com, Assem M. Khamis¹

amk88@mail.aub.edu, Abdul Sattar Raslan³ anr06@mail.aub.edu, Sanaa Badour⁴

badoursa@hotmail.com, Arnav Agarwal^{5,6} arnav.agarwal@mail.utoronto.ca, Fadel

Alturki³ fma46@mail.aub.edu, Gordon Guyatt⁶ guyatt@mcmaster.ca, Fadi El-Jardali^{6,7,8}

fe08@aub.edu.lb, Elie A. Akl^{1,4,6} ea32@aub.edu.lb

¹ Clinical Research Institute, American University of Beirut Medical Center, Beirut, Lebanon

²Center for Systematic Reviews for Health Policy and Systems Research, American University of Beirut, Beirut, Lebanon

³ Faculty of Medicine, American University of Beirut, Beirut, Lebanon

⁴Department of Internal Medicine, American University of Beirut Medical Center, Lebanon

⁵Department of Medicine, University of Toronto, Toronto, Ontario, Canada

⁶Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada

⁷Knowledge to Policy (K2P) Center, Faculty of Health Sciences, American University of Beirut, Lebanon

⁸Department of Health Management and Policy, Faculty of Health Sciences, American University of Beirut, Lebanon

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Corresponding author:

Elie A. Akl, MD, MPH, PhD

Department of Internal Medicine

American University of Beirut Medical Center

P.O. Box: 11-0236

Riad-El-Solh Beirut 1107 2020

For peer review only

Abstract

Objectives: The objective of this study was to assess the frequency and types of conflict of interest (COI) disclosed by authors of primary studies of Health Policy and Systems Research (HPSR).

Design: We conducted a cross sectional survey using standard systematic review methodology for study selection and data extraction. We conducted descriptive analyses.

Setting: We collected data from papers published in 2016 in “health policy and service journals” category in Web of Science database.

Participants: We included primary studies (e.g., randomized controlled trials, cohort studies, qualitative studies) of HPSR published in English in 2016 peer-reviewed health policy and services journals. .

Outcome measures: Reported COI disclosures including whether authors reported COI or not, form in which COI disclosures were provided, number of authors per paper that report any type of COI, number of authors per paper that report specific types and subtypes of COI.

Results: We included 200 eligible primary studies of which 132 (66%) included COI disclosure statements of authors. Of the 132 studies, 19 studies (14%) had at least one author reporting at least one type of COI and the most frequently reported type was individual financial COI (n=15, 11%). None of the authors reported individual intellectual COIs or personal COIs. Financial and individual COIs were reported more frequently compared with non-financial and institutional COIs.

Conclusion: A low percentage of HPSR primary studies included authors reporting COI. Non-financial or institutional COIs were the least reported types of COI.

Keywords: conflict of interest, health policy, health systems

Strengths and limitations of this study

- This is the first study to assess the frequency and types of COI disclosed by authors of primary studies of HPSR.
- The study used a rigorous methodology that included a search strategy specific to health policy and services journals and duplicate study selection and data abstraction processes.
- We used a comprehensive framework for the classification of COI.
- The study focused on reported COI, thus these statements depend on journals COI policy requirements, and whether authors’ disclosures are accurate or complete remains uncertain.

Background

Evidence-informed health policymaking aims to ensure that policymaking is well-informed by the best available evidence¹. Evidence from Health Policy and Systems Research (HPSR) can inform health system policy decisions including who delivers health services and where, and how these services are financed and organized^{2,3}. Furthermore, policymakers are increasingly recognizing the importance of the use of research evidence in improving health, reducing health inequities and contributing to economic development^{4,5}. However, conflict of interest (COI) of researchers may influence the conduct and reporting of HPSR.

COI is defined as “a financial or intellectual relationship that may impact an individual’s ability to approach a scientific question with an open mind”⁶. For instance, one study assessing the frequency and influence of financial COI on economic analyses in oncology found that the studies disclosing financial COI directly or indirectly consistently supported the sponsor’s product⁷. Additionally, Forsyth et al. found that opinion articles skeptical of the use of systematic reviews for policy-making were more likely to have industry ties than articles supportive of their use⁸.

Reporting of COI in HPSR is important given its potential influence on public policy and decision-making. We previously assessed the reporting of COI in HSPR systematic reviews⁹. We found that 20% of those reviews did not include a COI disclosure statement, and only 15% of disclosure statements reported the existence of any COI. Furthermore, the reporting of COI in primary studies is important for both policy makers,

relying on their findings for decision making, as well for authors of systematic reviews assessing the potential bias associated with the COI of study investigators ¹⁰. Therefore, this study aims to assess the types and frequency of COI disclosed by authors of primary studies of HPSR.

Methods

Design overview and definitions

We conducted a cross-sectional survey using standard systematic review methodology for study selection and data extraction. We defined COI disclosure as the reporting of whether a COI exists or not. We classified the types of disclosed COIs as shown in figure 1 and detailed in S1 appendix. Our classification of COIs relies on a framework informed by a literature review, the findings of recent studies assessing COIs reported by authors of clinical systematic reviews, HPSR systematic reviews and randomized controlled trials ^{9 11 12} and the International Committee of Medical Journal Editors (ICMJE) COI disclosure form¹³. We used the word “*loogly*” to label “*any additional statement in the COI disclosure that attempts to downplay a disclosed relationship by suggesting that it is unrelated to COP*” (e.g., ‘this relationship did not influence the content of the manuscript’) ¹¹.

Insert Figure 1 here

Figure 1: Classification of conflicts of interest

Eligibility criteria

We included articles meeting the following eligibility criteria:

- Type of study: primary studies (e.g., randomized controlled trials, cohort studies, qualitative studies). We excluded systematic and literature reviews, case studies, technical reports, conference reports, proceedings, editorials and opinion pieces; Type of field: health policy and systems research; we used the taxonomy of health systems topics used to code Health Systems Evidence (HSE) database of McMaster Health Forum to assess eligibility: governance, financial, delivery arrangements, and implementation strategies^{14 15}. Governance arrangements cover five topics: policy authority, organizational authority, commercial authority, professional authority, and consumer & stakeholder involvement. Financial arrangements include topics on financing systems, funding organizations, remuneration providers, purchasing products & services and incentivizing consumers. Delivery arrangements cover topics related to how care is designed to meet consumers' needs, by whom care is provided, where care is provided, with what supports is care provided. Implementation strategies comprise topics on consumer-targeted strategy, provider-targeted strategy and organization-targeted strategy.
- Articles published in English in 2016.

Search strategy

We searched for papers published in peer-reviewed health policy and services journals.

We ran the search in the Web of Science database limiting to “Health Policy and Services” journal category, “article” document type, English language and to the year 2016. S2 appendix presents the detailed search strategy.

Selection process

We drew a random sample of 200 papers from the set of citations retrieved by the search to undergo the selection process using an online random sequence generator (www.random.org/sequences). Citations were exported to EndNote™ X7.5 software (Thomson Reuters, Philadelphia, PA, USA). Reviewers completed calibration exercises before starting the selection process. Two reviewers screened title and abstracts for eligibility in duplicate and independently using EndNote. We ensured that papers retrieved by our search were effectively on HPSR. We retrieved the full text of citations judged as potentially eligible by at least one of the two reviewers. The two reviewers screened the full texts in duplicate and independently. The reviewers resolved their disagreements by discussion, and consulted a third reviewer when consensus could not be reached. We used a standardized and pilot tested full text screening form. We recorded reasons for exclusion and summarized the selection process results in a PRISMA study flow diagram ¹⁶.

Data extraction process

We developed and pilot-tested a standardized data extraction form with detailed instructions (see S3 appendix). Two teams of eight reviewers completed calibration exercises and extracted data in duplicate and independently. Reviewers extracted study data using Research Electronic Data Capture (REDCap) tool, a secure, web-based application designed to support data capture for research studies ¹⁶. The reviewers

compared results and resolved disagreements through discussion, or with the help of a third person when consensus could not be reached.

Extracted data

We extracted the following general characteristics of each article:

- Number of authors;
- Reported affiliation(s) of first and last author (private or public academic institution, government, not-for-profit organization, private-for-profit, intergovernmental);
- Country of affiliation of the first author and its classification (as per World Bank list of economies issued in September 2016);
- Health systems arrangement of the paper (governance, financial, delivery arrangements, and implementation strategies).

We extracted the following characteristics of the reported COI disclosures (as defined above):

- Whether authors reported COI or not;
- Form in which COI disclosures were provided (a narrative statement, an online document, available upon request);
- Number of authors per paper that report any type of COI;
- Number of authors per paper that report each specific type of COI, and when applicable, the different subtypes of COI;

- Whether the paper reports relevant characteristics of the COI (source, monetary value, duration);
- Whether individuals other than the authors provided COI disclosures (e.g. editors, peer-reviewers, external writers, others).

We extracted information the following information on the characteristics of the journal:

- Impact factor
- Existence of a COI disclosure policy

Data analysis

For eligible articles, we conducted descriptive analyses, focusing on the reported COI disclosures. For continuous variables, we present summary data as medians and quartiles since the application of the Kolmogorov– Smirnov (K–S) test did not demonstrate normality. We presented the results for categorical variables as frequencies and percentages, and analyzed them using the Chi-square test or, if the expected event number proved less than 5, the Fisher’s Exact test. We considered a p-value of < 0.05 as statistically significant. We performed the analysis using SPSS, version 21.0 for Windows (SPSS INC., Chicago, IL, USA).

Results

Out of the 2,648 citations identified, we included 200 eligible primary studies that were published in 55 “Health Policy & Services” journals. Figure 2 shows the study flow diagram.

Insert Figure 2

Figure 2: Study flow diagram

General characteristics of the included primary studies

Table 1 presents the general characteristics of the included primary studies. The median number of authors per study was four. Most studies were conducted by authors affiliated with institutions located in high-income countries (92%) and addressed the topic of delivery arrangements (72%). Most first authors and last authors were affiliated with public academic institutions (68% and 65% respectively).

Table 1: General characteristics of the included primary studies (N=200)

	Overall N (%)
Number of authors; Median (Interquartile range)	4 (3 – 6)
Classification of the country of the institution to which the first author is affiliated:	
<i>High income</i>	183 (92)
<i>Upper middle income</i>	10 (5)
<i>Lower middle income</i>	4 (2)
<i>Low income</i>	3 (2)
Affiliation of first author *	
<i>Public academic institution</i>	135 (68)
<i>Private academic institution</i>	46 (23)
<i>Government</i>	18 (9)
<i>Not-for-profit organization</i>	23 (12)
<i>Private-for-profit</i>	2 (1)

<i>Intergovernmental</i>	1 (1)
Affiliation of last author *	
<i>Public academic institution</i>	129 (65)
<i>Private academic institution</i>	51 (26)
<i>Government</i>	21 (11)
<i>Not-for-profit organization</i>	20 (10)
<i>Private-for-profit</i>	3 (2)
<i>Intergovernmental</i>	0 (0)
Type of Health Systems Arrangement *	
<i>Delivery arrangement</i>	143 (72)
<i>Implementation strategies</i>	25 (13)
<i>Governance arrangement</i>	23 (12)
<i>Financial arrangement</i>	67 (34)

* Studies may have more than one option that applies.

Characteristics of the reported COI disclosures

Of the 200 primary studies, 66% (132/200) included COI disclosure statements of authors.

All but one study provided COI disclosures narratively in the main document; the single study provided them in an online form that was not accessible. None of the included studies reported COI by individuals other than the authors (e.g. editors or peer-reviewers).

Table 2 presents the reporting of the different types of COI in the 132 studies that included COI disclosure statements. Of these 132 studies that included COI disclosure statements, 19 (14%) had at least one author reporting at least one type of COI while 113 (86%) studies had their authors reporting that they had no conflict of interest. The most frequently reported type was individual financial COI (n=15, 11%), with the median percentage of authors reporting this type of COI being 25%. None of the authors reported individual intellectual COIs or personal COIs. Of the 132 primary studies that provided COI disclosure statements, more had at least one author reporting financial COIs compared to non-financial COIs (n=16; 12% versus n=3; 2%; p-value=0.04). More studies had at least one author reporting individual COIs compared to institutional COIs (n=15; 11% versus n=5; 4%; p-value=0.01).

Table 2: Reporting by primary study authors of the different types of conflict of interest (COI) (N=132)

	Studies with at least one author reporting a specific type of COI *; n (%)	Distribution of the percentage of authors per study reporting that type of COI §; Median (Interquartile range)
--	---	---

At least one type	19 (14)	25 (17 – 50)
Individual financial (direct benefit)	15 (11)	25 (15 – 50)
Individual financial (benefit through professional status)	0 (0)	N/A
Individual intellectual	0 (0)	N/A
Individual personal	0 (0)	N/A
Institutional financial	2 (2)	a
Institutional intellectual	3 (2)	b
Institutional cultural	0 (0)	N/A
“Other types” §	4 (3)	30 (18 – 85)
Provided a “loogly statement”	3 (2)	c

* One study can have authors reporting more than one type of COI.

§ Calculated using the number of papers with at least one author reporting the specific type of COI (i.e., papers counted in the preceding column) as the denominator.

\$ “Other types” of COIs included: ‘implementing national clinical audit’ (n=1), ‘non-compensated affiliations’ (n=1), ‘attended meetings’ (n=1), and relationship with a publishing entity (n=1). We consider these as individual and non-financial types of COI.

^a Authors of only 2 studies reported institutional financial COI, with the percentages being 20% and 100%.

^b Authors of only 3 studies reported institutional intellectual COI, with the percentages being 20%, 25%, and 33%.

^c Authors of only 3 studies provided a “loogly statement”, with the percentages being 10%, 25% and 100%.

N/A=Not applicable

Individual financial COI: Table 3 presents the reporting of the different subtypes of individual financial COI in the 15 primary studies with at least one author reporting individual financial COI. The two most frequently reported subtypes were ‘personal fees’

(n=9; 60%) and ‘grant’ (n=6, 40%). The median percentages of authors reporting these two subtypes were 20% and 18% respectively.

Table 3: Reporting of primary study authors of different subtypes of individual financial conflict of interest (COI) (N=15)

	Studies with at least one author reporting the subtype of individual financial COI *; n (%)	Distributions of the percentage of authors per study reporting that subtype of COI §; Median (Interquartile range)
Grant	6 (40)	18 (9 – 27)
Employment	2 (13)	^a
Personal fees (other than employment)	9 (60)	20 (12 – 38)
Non-monetary support	1 (7)	^b
Study supplies/services	0 (0)	N/A
Patent(s)	0 (0)	N/A
Stocks, bonds, stock options, other securities	3 (20)	^c
“Other subtypes”	0 (0)	N/A

* One study can have authors reporting more than one type of COI.

§ Calculated using the number of papers with at least one author reporting the specific type of COI (i.e., papers counted in the preceding column) as the denominator.

^a Authors of only 2 studies reported “Employment”, with the percentages being 50% and 100%.

^b Authors of only 1 study reported “Non-monetary support”, with the percentage being 17%.

^c Authors of only 3 studies reported “Stocks, bonds, stock options, other securities”, with the percentages being 20%, 25% and 33%.

N/A=Not applicable

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Of the 15 studies with at least one author reporting individual financial COI, 14 reported the source of financial COI. Only two of these 14 studies specified the relationship of the source to the field under study; in both cases, the sources produced a product not the subject of the study but under the same field. Only one of the 15 studies reported on the timing of the conflicted relationship relative to the conduct of the study; in that case, the relationship occurred during the conduct of the study. None of the studies reported on the monetary value of the financial COI.

Characteristics of the Journals

The median impact factor of the 55 journals that published the included primary studies was 1.66 (IQR=1.36-2.41). Ninety-six percent (53/55) of the journals had a COI disclosure policy. Of the 68 papers that did not include a COI statement, 90% (61/68) were published in journals that did have a COI disclosure policy. We provided the list of the 55 journals that published the included primary studies in S4 appendix.

Discussion

Summary of findings

In summary, 66% of 200 HPSR primary studies included COI disclosure statements of authors, with only one using an inaccessible online disclosure form. Of these studies, 14% had at least one author reporting at least one type of COI. Most frequently, authors reported individual financial COI. Very few studies reported non-financial or institutional COIs. The two most frequently reported subtypes of individual financial COI were ‘personal fees’ and ‘grant’. None of the studies reported on the monetary value of the

financial COI, or provided disclosure by individuals other than the authors such as editors or reviewers.

Strengths and limitations

This is the first study to assess the frequency and types of COI disclosed by authors of primary studies of HPSR. We have used a rigorous methodology that included a search strategy specific to health policy and services journals and duplicate study selection and data abstraction processes. We used a comprehensive framework for the classification of COI used in previous studies^{9 11 12}. Our study focused on reported COI, thus these statements depend on journals COI policy requirements, and whether authors' disclosures are accurate or complete remains uncertain.

Comparison to other studies

Our findings, in relation to similar studies, demonstrate that COI disclosure statements are less frequently included in HPSR primary studies (66%) compared to HPSR systematic reviews (80%), clinical randomized controlled trials (94%), and clinical systematic reviews (97%) (figure 3)^{9 11 12}. Factors that may be contributing to these differences include the less rigorous COI policies in HPSR journals compared to Core Clinical journals, and potentially a less strict implementation: 93% of HPSR journals (including the 55 journals that published the primary studies included in this study) have a COI disclosure policy compared to 99% for Core Clinical journals^{17 18}.

The percentage of authors reporting any type of COI in HPSR primary studies (14%) was comparable to that of HPSR systematic reviews (15%). However, that percentage is much lower compared to that of clinical systematic reviews (41%) and clinical trials (57%)^{9 11}
¹². Possible explanations for this low rate of disclosure could be that HPSR authors may have less COIs than authors in the clinical field, HPSR authors are less aware of what constitute COI in their field or self-reporting is an inadequate and inaccurate form of disclosure. Indeed, an increasing number of studies is using resources such as the Open Payment database to verify the accuracy of the COI disclosures of health researchers¹⁹⁻²². They are consistently showing that researchers tend to underreport their conflicts of interest (up to 81% in one study²³).

Reporting of financial COI was higher than non-financial COI in HPSR primary studies. This is consistent with the findings of previous studies that focused on COI reporting in HPSR systematic reviews, clinical systematic reviews, and randomized controlled trials⁹
^{11 12}. Although this might reflect how frequently these types of COI exist, it might also be that authors are less aware of the concept of non-financial COI, or of what exactly qualifies as a non-financial COI. Another explanation could be related to the extent of use of standard COI disclosure forms: we found that only one study used a standardized form to report COI, compared to 12% in clinical trials¹².

Insert Figure 3 here

Figure 3: chart comparing the reporting of financial and non-financial COI in different types of publications. The denominator for the reporting of the different types of COI is the number of studies that included a COI disclosure statement.

Implications for practice and research

As HPSR may be used to inform policy decisions, COI of HPSR authors may bias their research output and subsequently lead to misguided public policies and decisions^{24 25}. For example, Bes-Rastrollo et al. found that financial COI may bias findings of systematic reviews of the effects of sugar-sweetened beverages consumption on weight gain and obesity²⁶. In turn, such biased conclusions might adversely influence policymaking related to regulation of sugar-sweetened beverages. Consequently, the appropriate disclosure and management of COIs are essential for the credibility and trust in HPSR and hence, might increase its uptake in policymaking. For that reason, HPSR journals to strengthen their COI disclosure policies, and the implementation of existing policies. One approach to help authors better recognize and disclose their COIs would be to develop a standardized COI disclosure form similar to that of the ICMJE but more specific to health policy and systems research. Journals publishing HPSR should also consider collecting and publishing the COIs of editors and peer-reviewers. Future research should investigate the reasons behind the higher reporting of financial COI compared with non-financial COI in HPSR primary studies. Investigate of the accuracy and completeness of reporting of COI may also provide insight into the low rates of disclosed COI.

Contributions: MBH, LBK, FEJ, GG, and EAA conceived and designed the study. MBH coordinated the study throughout. EAA had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. MBH and LBK ran the search and study selection processes. MBH, LBK, MAG, AK, ASR, SB, AA, and FA extracted the data. MBH, LBK, and EAA analyzed and interpreted the data. MBH and LBK wrote the first draft of the manuscript with EAA. All authors critically revised the manuscript and approved the final version. The lead author EAA affirms that this manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Funding: This work was supported by the American University of Beirut Faculty of Medicine’s Medical Practice Plan (MPP) funds.

Acknowledgements: None

Competing interests: Maram B. Hakoum, Gordon Guyatt, and Elie A. Akl have competing interests related to their research in the area of conflicts of interest.

Ethics approval: The study involves no human subjects and requires no ethical approval.

Patient and Public Involvement: It was not appropriate or possible to involve patients or the public in this work.

Data sharing statement: All data relevant to the study are included in the article or uploaded as supplementary information.

References

1. Oxman AD, Lavis JN, Lewin S, et al. SUPPORT Tools for evidence-informed health Policymaking (STP) 1: What is evidence-informed policymaking? *Health research policy and systems* 2009;7 Suppl 1:S1. doi: 10.1186/1478-4505-7-s1-s1 [published Online First: 2009/12/19]
2. Gilson L, Hanson K, Sheikh K, et al. Building the Field of Health Policy and Systems Research: Social Science Matters. *PLoS Medicine* 2011;8(8):e1001079. doi: 10.1371/journal.pmed.1001079
3. Koon AD, Rao KD, Tran NT, et al. Embedding health policy and systems research into decision-making processes in low- and middle-income countries. *Health research policy and systems* 2013;11(1):30. doi: 10.1186/1478-4505-11-30
4. Lavis JN, Posada FB, Haines A, et al. Use of research to inform public policymaking. *The Lancet*;364(9445):1615-21. doi: 10.1016/S0140-6736(04)17317-0
5. El-Jardali F, Lavis JN, Ataya N, et al. Use of health systems evidence by policymakers in eastern mediterranean countries: views, practices, and contextual influences. *BMC Health Services Research* 2012;12(1):200. doi: 10.1186/1472-6963-12-200
6. Schunemann HJ, Osborne M, Moss J, et al. An official American Thoracic Society Policy statement: managing conflict of interest in professional societies. *American journal of respiratory and critical care medicine* 2009;180(6):564-80. doi: 10.1164/rccm.200901-0126ST
7. Jang S, Chae YK, Majhail NS. Financial Conflicts of Interest in Economic Analyses in Oncology. *American Journal of Clinical Oncology* 2011;34(5):524-28. doi: 10.1097/COC.0b013e3181f4799b
8. Forsyth SR, Odierna DH, Krauth D, et al. Conflicts of interest and critiques of the use of systematic reviews in policymaking: an analysis of opinion articles. *Systematic reviews* 2014;3:122. doi: 10.1186/2046-4053-3-122 [published Online First: 2014/11/25]
9. Bou-Karroum L, Hakoum MB, Hammoud MZ, et al. Reporting of Financial and Non-financial Conflicts of Interest in Systematic Reviews on Health Policy and Systems Research: A Cross Sectional Survey. *International journal of health policy and management* 2018;7(8):711-17. doi: 10.15171/ijhpm.2017.146
10. Elia N, von Elm E, Chatagner A, et al. How do authors of systematic reviews deal with research malpractice and misconduct in original studies? A cross-sectional analysis of systematic reviews and survey of their authors. *BMJ Open* 2016;6(3):e010442. doi: 10.1136/bmjopen-2015-010442
11. Hakoum MB, Anouti S, Al-Gibbawi M, et al. Reporting of financial and non-financial conflicts of interest by authors of systematic reviews: a methodological survey. *BMJ Open* 2016;6(8):e011997. doi: 10.1136/bmjopen-2016-011997
12. Hakoum MB, Jouni N, Abou-Jaoude EA, et al. Authors of Clinical Trials Reported Individual and Financial Conflicts of Interest More Frequently than Institutional and non-financial Ones: a Methodological Survey. *J Clin Epidemiol* 2017 doi: 10.1016/j.jclinepi.2017.04.002

13. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. Secondary Uniform requirements for manuscripts submitted to biomedical journals December, 2015. http://www.icmje.org/coi_disclosure.pdf.

14. About HSE. : Health Systems Evidence; [Available from: <https://www.healthsystemsevidence.org/about>. 2016.

15. Lavis JN, Wilson MG, Moat KA, et al. Developing and refining the methods for a 'one-stop shop' for research evidence about health systems. *Health research policy and systems* 2015;13:10. doi: 10.1186/1478-4505-13-10 [published Online First: 2015/05/15]

16. Harris PA, Taylor R, Thielke R, et al. Research Electronic Data Capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of biomedical informatics* 2009;42(2):377-81. doi: 10.1016/j.jbi.2008.08.010

17. Khamis AM, Hakoum MB, Bou-Karroum L, et al. Requirements of health policy and services journals for authors to disclose financial and non-financial conflicts of interest: a cross-sectional study. *Health research policy and systems* 2017;15(1):80. doi: 10.1186/s12961-017-0244-2

18. Shawwa K, Kallas R, Koujanian S, et al. Requirements of Clinical Journals for Authors' Disclosure of Financial and Non-Financial Conflicts of Interest: A Cross Sectional Study. *PLoS ONE* 2016;11(3):e0152301. doi: 10.1371/journal.pone.0152301

19. Boddapati V, Fu MC, Nwachukwu BU, et al. Accuracy Between AJSM Author-Reported Disclosures and the Centers for Medicare and Medicaid Services Open Payments Database. *The American journal of sports medicine* 2018;46(4):969-76. doi: 10.1177/0363546517750124 [published Online First: 2018/02/01]

20. Cherla DV, Viso CP, Olavarria OA, et al. The Impact of Financial Conflict of Interest on Surgical Research: An Observational Study of Published Manuscripts. *World Journal of Surgery* 2018;42(9):2757-62. doi: 10.1007/s00268-018-4532-y

21. Jimbo M, Granberg CF, Osumah TS, et al. Discrepancies in Self-Reported and Actual Conflicts of Interest for Robotic Pediatric Urological Surgery. *The Journal of urology* 2019;201(2):393-99. doi: 10.1016/j.juro.2018.07.043 [published Online First: 2018/07/28]

22. Luce EA, Jackman CA. Disclosure of Financial Conflicts of Interest in Plastic and Reconstructive Surgery. *Plastic and reconstructive surgery* 2017;140(3):635-39. doi: 10.1097/prs.0000000000003598 [published Online First: 2017/08/26]

23. Patel SV, Yu D, Elsolh B, et al. Assessment of Conflicts of Interest in Robotic Surgical Studies: Validating Author's Declarations With the Open Payments Database. *Annals of surgery* 2018;268(1):86-92. doi: 10.1097/sla.0000000000002420 [published Online First: 2017/07/13]

24. Mandrioli D, Kearns CE, Bero LA. Relationship between Research Outcomes and Risk of Bias, Study Sponsorship, and Author Financial Conflicts of Interest in Reviews of the Effects of Artificially Sweetened Beverages on Weight

- 1
2
3 Outcomes: A Systematic Review of Reviews. *PLOS ONE* 2016;11(9):e0162198.
4 doi: 10.1371/journal.pone.0162198
5
6 25. Scollo M, Lal A, Hyland A, et al. Review of the quality of studies on the economic
7 effects of smoke-free policies on the hospitality industry. *Tobacco Control*
8 2003;12(1):13-20. doi: 10.1136/tc.12.1.13
9
10 26. Bes-Rastrollo M, Schulze MB, Ruiz-Canela M, et al. Financial conflicts of interest
11 and reporting bias regarding the association between sugar-sweetened
12 beverages and weight gain: a systematic review of systematic reviews. *PLoS*
13 *medicine* 2013;10(12):e1001578-e78. doi: 10.1371/journal.pmed.1001578
14 [published Online First: 12/31]
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

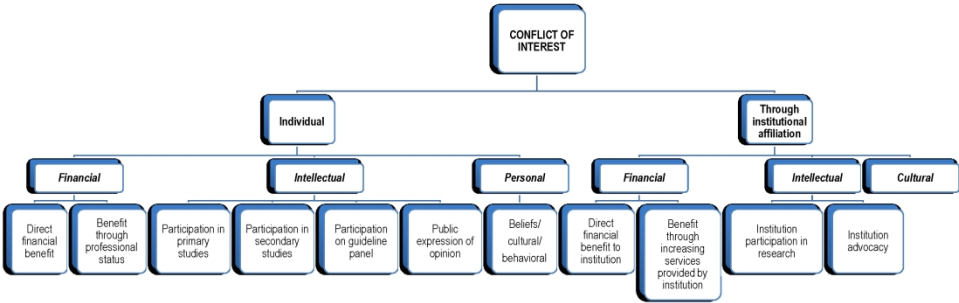


Figure 1: Classification of conflicts of interest

240x130mm (300 x 300 DPI)

2,648 records identified
by the search strategy
(search run on 11/07/2016)

500 records randomly sampled

500 titles and abstracts
assessed for eligibility

257 records excluded

243 full-text papers
assessed for eligibility

43 records excluded
38 not identified as
primary studies
5 not on HPSR

200 papers included

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

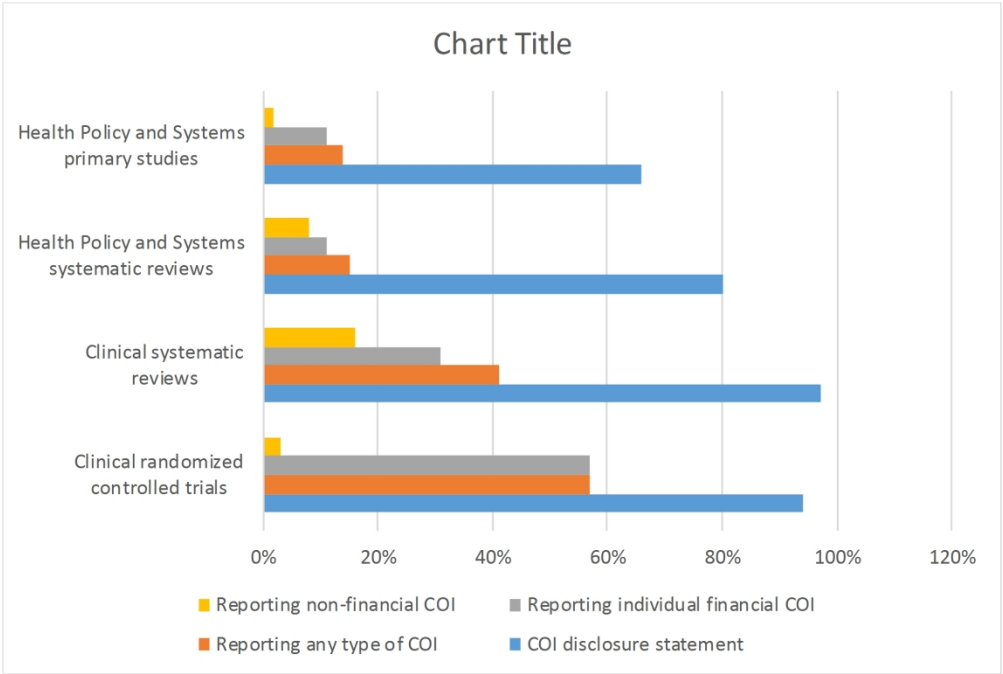


Figure 3: chart comparing the reporting of financial and non-financial COI in different types of publications. The denominator for the reporting of the different types of COI is the number of studies that included a COI disclosure statement.

198x133mm (300 x 300 DPI)

S1 Appendix: Classification of conflicts of interest

Conflicts of interest can be individual or exist through institutional affiliations:

- Individual COIs. Types of individual COI include financial, intellectual and personal COIs.
- Types of institutional COI include financial, intellectual and cultural COIs.

Part 1: Classification of individual financial COI

Part 1a: Individual financial COI with direct financial benefit

Definition:

Individual financial COI with direct financial benefit arises from any payment, research funding, consultancy, advisory board membership, and the like from the manufacturer of a drug or device or service under consideration. This type of COI may involve the individuals themselves, their families or a business they own. Typically, a timeframe of three to five years is considered for these COIs.

Grant

There could be a differentiation whether the grant is going to the investigator or to his/her institution. Types: grant; salary for research; contract; fellowship; unrestricted educational funding; peer-reviewed grant funding

Employment

Types: former employment; current employment; stipend; salary

Personal fees (other than employment)

Types: honoraria, royalties, fees for consulting, lectures, speakers' bureaus, expert testimony, presentations, editorial work, manuscript preparation, trial involvement, management, educational support, production of books, article research, scientific meetings, entertainment, gift, charitable contribution, other affiliations (e.g. advisory board, steering committee membership, supported by another party for holding a chair at one's institution)

Non-monetary support	<i>Types: travel paid; writing assistance; administrative support; food and beverage</i>
Study supplies/services	
Patent(s)	
Stocks, bonds, stock options, other securities (e.g. equity)	
Other forms	

Part 1b: Individual financial COI with benefit through professional status

Definition: Individual financial COI with benefit through professional status arises when an individual is "engaged in a specified activity as one's main paid occupation" or "a member of a professional group of individuals".
<i>e.g. an author that is a dietician conducts a study looking at advice vs. no advice from a dietician; an author that provides colonoscopy services; an author that works at a warfarin clinic</i>

Part 2: Classification of individual intellectual COI

Definition: Individual intellectual COI arises when an individual participates in scholarly activities related to the issue under consideration, or when an individual has taken a position or has an opinion and expresses it in a statement publicly. Such activities may result in an emotional attachment to a particular interpretation of evidence or position regarding optimal course of action.	
Participation in primary studies	<i>e.g. randomized controlled trials; case-control studies, observational studies, qualitative studies</i>
Participation in secondary studies	<i>e.g. systematic reviews</i>
Participation on guideline panel	<i>e.g. Chair of American Heart Association Get With The Guidelines Steering Committee</i>

Public expression of opinion	<i>e.g. textbook; review article; editorial; presentation</i>
------------------------------	---

Part 3: Classification of individual personal COI

Definition:

when an individual has personal opinions or conditions that concern one's private life, relationships, and emotions rather than one's career or public life.

Beliefs (religious, political, philosophical)	<i>e.g. an author against organ donation or abortion attributed to personal religious beliefs</i>
---	---

Personal characteristics (gender, age, race, physical/psychiatric condition, sexual orientation)	<i>e.g. an author with a physical disability conducting a study on the benefit of physical rehabilitation</i>
--	---

Part 4: Classification of institutional financial COI

Part 4a: Institutional financial COI with direct financial benefit to the institution

Definition:

Institutional financial COI arises when an institution, to which an individual belongs, has a relationship with the manufacturer of a drug or device or service under consideration. Such institutions include academic medical centers and professional societies.

Seeking and receiving gifts, endowments, or grants from companies, for example, a gift of an endowed university chair	<i>Types: grants for research/fellowship/salary support; merit awards; endowments; patent funds; educational fees; funds for author activities (speaker fee, consultancy, honoraria, board membership, testimony, writing); funds for drug/equipment supplies</i>
---	---

Conduct of research within the institution that relates to the issue under consideration and could affect the value of the institution's patents or its equity positions or options in biotechnology, pharmaceutical, or medical device companies

Senior officials who act on behalf of the institution have personal financial interests related to the issue under consideration

--	--

Part 4b: Institutional financial COI with benefit through increasing services provided by the institution

<p>Definition: when an institution employs professionals who advocate for clinical services related to the issue under consideration but don't provide those services themselves.</p>

Part 5: Classification of institutional intellectual COI

<p>Definition: Institutional intellectual COI arises when an institution/organization, to which an individual belongs, focuses or funds research on a specific topic, or arises when an individual (paid employee or unpaid member) belongs to an institution/organization that clearly advocates for the issue under consideration.</p>	
<p>Institution participation in research</p>	<p><i>e.g. an author works at a hospital which is enrolling participants in a trial on a certain topic; an author is a member of an organization that has a research focus on a certain topic</i></p>
<p>Institution advocacy when the institution:</p>	<ol style="list-style-type: none"><i>1. is an advocacy group that clearly advocates for the issue under consideration</i><i>2. has advocacy related to the issue under consideration as part of its mission, objectives, work, or stated position (i.e. position statement, editorial, blog, amicus brief, or legislature or legal testimony)</i><i>3. shows "public support for or recommendation of a particular cause or policy"</i><i>4. has senior officials who act on its behalf and have COI related to the issue under consideration</i>

Part 6: Classification of institutional cultural COI

Definition:

Institutional cultural COI arises when an individual (paid employee or unpaid member) belongs to an institution/organization that has a specific cultural identity (e.g. catholic university).

For peer review only

1
2
3 S2 Appendix: Search strategy
4
5

6
7
8 Web of Science search strategy for health policy and services papers
9

- 10 1. Advanced search for “WC=(Health Policy & Services)”
11
12 2. Limit to “English”
13
14 3. Refine document types to “article”
15
16 4. Limit time span to: “01/01/2016 to present”
17
18 5. Select Social Sciences Citation Index
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Data Abstraction Form (COI in HPS studies)

Record Number

Last name of the First Author

Study Title

Journal number

1- Please select your name below

1.A- Reviewer name

- ☐ Abdul Sattar
☐ Arnav
☐ Assem
☐ Lama
☐ Maram
☐ Mounir
☐ Sanaa
☐ Fadel

2- General characteristics of the study

2.A.1- Number of authors

2.A.2a- Please select the reported affiliation(s) by the FIRST author

- ☐ Private academic/university
☐ Public academic/university
☐ Government
☐ Not for profit organization
☐ Private for profit
☐ Intergovernmental

2.A.2b- Please select the reported affiliation(s) by the LAST author

- ☐ Private academic/university
☐ Public academic/university
☐ Government
☐ Not for profit organization
☐ Private for profit
☐ Intergovernmental

2.B.1- Please insert the Country of the affiliation of the first author:

2.B.2- Country classification (please see Supplementary File):

- ☐ High income
☐ Upper-middle income
☐ Lower-middle income
☐ Low income

3- Funding of the study

3.A- Is the study funded?

- ☐ Funded
☐ Not funded
☐ Not reported

3.B- Reported Source(s) of Funding/Support (check all that apply)

- ☐ 1. Internally funded
☐ 2. Governmental
☐ 3. Private for Profit
☐ 4. Private not for Profit with evidence of support by Private for Profit that is a Drug/Device Industry
☐ 5. Private not for Profit with evidence of support by Private for Profit that is NOT a Drug/Device Industry
☐ 6. Private not for Profit with no evidence of support by Private for Profit
☐ 7. Intergovernment
(Note: 1 for Internal sources of funding; 2-6 for External sources of funding)

3.C.1a- Does the paper explicitly report whether the funder/sponsor was involved in the following?

	Not involved	Involved	Not reported
1. Protocol/design of the study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Data collection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Data analysis/ interpretation/ management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Funded a writer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Preparation of the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Review of the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Approval of the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Decision to submit the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Verified data accuracy/fact checking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Auditing of study conduct	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Conduct of study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Study oversight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Logistical support	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Team assembly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Other (please specify below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3.C.1b- If other, please specify

4- Conflict of Interest Disclosure

4.A- Does the paper report COI in the following forms? (check all that apply)

- ☐ Yes, narrative statement in the main document
☐ Yes, in an online document (accessible)
☐ Yes, in an online document (not accessible)
☐ Yes, available upon request
☐ No

4.A.1- Please copy and paste the quotation declaring COI from the main document

1 4.B.1a- The online document reports COI as (check all
2 that apply):

- ☐ Narrative statement
☐ ICMJE Uniform Disclosure Form
☐ Other form

3
4 4.B.1b- If other form, please specify _____
5

6 4.B.2- Please copy and paste the quotation declaring
7 COI from the online document _____
8

9 4.C.1- How many authors report any type of COI in the
10 Main document? _____
11

12 4.C.2- How many authors report any type of COI in the
13 Online document? _____
14

16 4.D- For how many authors:

17
18
19 4.D.1- Does the online document report more
20 disclosures than the main document? _____
21

22 4.D.2- Does the online document report less
23 disclosures than the main document? _____
24

25 4.D.3- Does the online document report the same
26 disclosure(s) as in the main document? _____
27

28 4.D.4- Does the online document report more details
29 than the main document for the same disclosure(s)? _____
30

31 4.D.5- Does the online document report less details
32 than the main document for the same disclosure(s)? _____
33

35 5- Disclosure(s) of Individual Financial COI (with direct financial benefit)

36
37
38 5.A- How many authors report COI related to any
39 subtype of individual financial COI (with direct
40 financial benefit)? _____
41

43 5.B- If any individual financial COI is reported, for how many authors does it relate to the 44 following subtypes?

45
46
47 5.B.1- Grant from source(s) same as funding source(s) _____
48

49 5.B.2a- Grant from source(s) different from funding
50 source(s) _____
51

52 5.B.2b- Please specify the source(s) that are
53 different from the funding source(s): _____
54

55 5.B.3- Employment _____
56

57 5.B.4- Personal fees (other than Employment) _____
58

59 5.B.5- Non-monetary support _____
60

5.B.6- Drug/Equipment supplies _____

5.B.7a- Patent(s) _____

Yes

No

☐☐

5.B.7b.1- Does the disclosure specify whether a patent relates to one of the interventions subject of the study?

☐☐

5.B.7b.2- Does the disclosure specify whether a interventions relates to the field but not any of the interventions subject of the study?

5.B.8- Stocks, bonds, stock options, other securities

5.B.9a- Other forms

5.B.9b- If other, please specify here:

5.C- Does the disclosure include the following?

5.C.1a- Source(s)

☐ Yes☐ No

5.C.1b- Does the paper specify whether:

5.C.1b.1- Any source(s) of COI produces one of the interventions subject of the study?

Yes

☐

No

☐

5.C.1b.2- Any source(s) of COI produces interventions not subject of the study but under the same field?

☐☐

5.C.2a- Monetary value

☐ Yes☐ No

5.C.2b- If monetary value is specified, please copy and paste the quotation here:

5.C.3a- Time period

☐ Yes☐ No

5.C.3b- If time period is specified, please select longest duration reported:

☐ During conduct of the study☐ 1 year☐ 2 years☐ 3 years☐ 4 years☐ 5 years☐ >5 years

6- Disclosure(s) of Individual Financial COI (with benefit through professional status)

6.A- How many authors report COI related to any subtype of individual financial COI (with benefit from professional status)? _____

6.B- Does the disclosure specify whether:

Yes

No

6.B.1- Any type(s) of Individual Financial COI (with benefit through professional status) relates to one of the interventions subject of the study?

☐☐

6.B.2- Any type(s) of Individual Financial COI (with benefit through professional status) relates to interventions not subject of the study but under the same field?

☐☐

7- Individual Intellectual COI Disclosure(s)

7.A- How many authors report on the following subtypes of Individual Intellectual COI?

7.A.1- Participation in primary studies _____

7.A.2- Participation in secondary studies _____

7.A.3- Participation in guideline panel(s) _____

7.A.4- Public expression of opinion _____

7.B- Does the disclosure specify whether:

Yes

No

7.B.1- Any type(s) of Individual Intellectual COI relates to one of the interventions subject of the study?

☐☐

7.B.2- Any type(s) of Individual Intellectual COI relates to interventions not subject of the study but under the same field?

☐☐

8- Individual Personal COI Disclosure(s)

8.A.1- How many authors report Individual Personal COI in any form? _____

8.A.2- If any form of Individual Personal COI is disclosed by any author, please copy and paste the quotation(s) here: _____

8.B- Does the disclosure specify whether:

Yes

No

8.B.1- Any type(s) of Individual Personal COI relates to one of the interventions subject of the study?

☐☐

8.B.2- Any type(s) of Individual Personal COI relates to interventions not subject of the study but under the same field?

☐☐

9- Institutional Financial COI Disclosure(s)

9.A.1- How many authors report Institutional Financial COI, with direct financial benefit to the institution? _____

9.A.2- How many authors report Institutional Financial COI, with benefit through increasing services provided by institution? _____

9.A.3- If any form of Institutional Financial COI is disclosed by any author, please copy and paste the quotation(s) here: _____

9.B- Does the disclosure include the following?

9.B.1a- Source(s)

☐ Yes☐ No

9.B.1b- Does the paper specify whether:

Yes

No

9.B.1b.1- Any source(s) of COI produces one of the interventions subject of the study?

☐☐

9.B.1b.2- Any source(s) of COI produces interventions not subject of the study but under the same field?

☐☐

9.B.2a- Monetary value

☐ Yes☐ No

9.B.2b- If monetary value is specified, please copy and paste the quotation here:

9.B.3a- Time period

☐ Yes☐ No

9.B.3b- If time period is specified, please select longest duration reported:

☐ During conduct of the study☐ 1 year☐ 2 years☐ 3 years☐ 4 years☐ 5 years☐ >5 years

10- Institutional Intellectual COI Disclosure(s)

10.A.1- How many authors report Institutional Intellectual COI related to institution participation in research?

10.A.2- How many authors report Institutional Intellectual COI related to institution advocacy?

10.A.3- If any form of Institutional Intellectual COI is disclosed by any author, please copy and paste the quotation(s) here:

10.B- Does the disclosure specify whether:

Yes

No

10.B.1- Any type(s) of Institutional Intellectual COI relates to one of the interventions subject of the study?

☐☐

1 10.B.2- Any type(s) of
2 Institutional Intellectual COI
3 relates to interventions not
4 subject of the study but under
5 the same field?
6
7
8

☐☐

11- Institutional Cultural COI Disclosure(s)

12 11.A.1- How many authors report Institutional
13 Cultural COI? _____
14

15 11.A.2- If any form of Institutional Cultural COI is
16 disclosed by any author, please copy and paste the
17 quotation(s) here: _____
18
19

11.B- Does the disclosure specify whether:

24 11.B.1- Any type(s) of
25 Institutional Cultural COI relates
26 to one of the interventions
27 subject of the study?
28

Yes

☐

No

☐

31 11.B.2- Any type(s) of
32 Institutional Cultural COI relates
33 to interventions not subject of
34 the study but under the same
35 field?
36
37
38

☐☐

12- Other COI Disclosure(s)

42 12.A- For COI disclosures that you could not
43 categorize, please specify the number of authors
44 (eg. 5 authors) for the uncategorized disclosures
45 then copy/paste the statement(s) here: _____
46
47

13- Non-Influential/Unrelated COI Disclosures

51 13.A- For COI disclosures that describe a
52 relationship (e.g., payment from drug company) then
53 include the loogly statement such as "this was
54 unrelated to the subject" or "but she did not
55 endorse..." or "this relationship did not influence
56 his decision": Please specify the number of authors
57 that include such a statement (eg, 5 authors) then
58 copy/paste the statement(s) here: _____
59
60

14- COI Disclosures by Individuals other than the authors

14.A- For Editor(s): is there a reference to a COI disclosure statement (available in the full-text, or as an accessible ICMJE form, or upon request)?

☐ Yes
☐ No

14.B- For Peer-reviewer(s): is there a reference to a COI disclosure statement (available in the full-text, or as an accessible ICMJE form, or upon request)?

☐ Yes
☐ No

14.C.1a- Does the paper report contribution by an external writer?

☐ Yes
☐ No

14.C.1b- If yes, is there a reference to a COI disclosure statement (available in the full-text, or as an accessible ICMJE form, or upon request) by the external writer?

☐ Yes
☐ No

14.D.1a- Does the paper provide COI disclosures by other individuals/groups (besides the authors, editors, peer-reviewers, external writers)?

☐ Yes
☐ No

14.D.1b- If yes, please copy/paste the statements here:

15- Requested COI Disclosures

Please skip this section (only for Maram to fill)

15.A- Was information on COI provided upon request?

☐ Yes
☐ No

15.B.1a- The provided document reports COI as (check all that apply):

☐ Narrative statement
☐ ICMJE Uniform Disclosure Form
☐ Other form

15.B.1b- If other form, please specify

15.C- For how many authors:

15.C.1- Does the provided document report more disclosures than the main document?

15.C.2- Does the provided document report less disclosures than the main document?

15.C.3- Does the provided document report the same disclosure(s) as in the main document?

15.C.4- Does the provided document report more details than the main document for the same disclosure(s)?

15.C.5- Does the provided document report less details than the main document for the same disclosure(s)?

S4 Appendix: List of 55 journals publishing the included primary studies

Health Affairs
BMJ Quality & Safety
Health Expectations
Implementation Science
Medical Care
Milbank Quarterly
Health Services Research
Medical Care Research And Review
Pharmacoeconomics
International Journal For Quality In Health Care
Health Policy And Planning
Administration and Policy in Mental Health and Mental Health Services Research
Quality Of Life Research
Human Resources for Health
Journal Of Health Economics
Psychiatric Services
European Journal Of Health Economics
Palliative & Supportive Care
Patient-Patient Centered Outcomes Research
Health And Quality Of Life Outcomes
Health Economics
Health Promotion International
Health Policy
Psychology Public Policy And Law
AIDS Care-Psychological And Socio-Medical Aspects Of AIDS/HIV
Journal of Health Services Research & Policy
BMC Palliative Care
Journal Of Aging And Health
American Journal Of Managed Care
Journal Of Interprofessional Care
Expert Review Of Pharmacoeconomics & Outcomes Research
Journal Of Behavioral Health Services & Research
Journal of Pediatric Health Care
BMC International Health and Human Rights
Health Care Management Review
Journal For Healthcare Quality
Journal Of Community Health
Health Communication
Health Care Management Science
Journal Of Health Politics Policy And Law
Qualitative Health Research
Journal Of Mental Health Policy And Economics
Disability And Health Journal

Journal Of Rural Health
Australian Journal of Primary Health
International Journal Of Health Planning And Management
Journal Of Healthcare Management
Community Mental Health Journal
Journal Of Health Care For The Poor And Underserved
Journal of Policy and Practice in Intellectual Disabilities
Quality Management In Health Care
Australian Health Review
International Journal Of Health Services
Inquiry-The Journal Of Health Care Organization Provision And Financing
International Journal of Health Economics and Management

BMJ Open

Reporting of Conflicts of Interest by Authors of Primary Studies on Health Policy and Systems Research: a Cross-sectional Survey

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-032425.R2
Article Type:	Original research
Date Submitted by the Author:	07-Apr-2020
Complete List of Authors:	Hakoum, Maram; American University of Beirut, Clinical Research Institute Bou-Karroum, Lama ; American University of Beirut Al-Gibbawi, Mounir; American University of Beirut Faculty of Medicine Khamis, Assem; American University of Beirut, Internal Medicine Raslan, Abdul Sattar ; American University of Beirut Badour, Sanaa ; American University of Beirut Medical Center Agarwal, Arnav; University of Toronto, Faculty of Medicine Alturki, Fadel ; American University of Beirut Guyatt, Gordon; McMaster University, Clinical Epidemiology and Biostatistics El-Jardali, Fadi; Department of Health Management and Policy, Faculty of Health Sciences, American University of Beirut, Beirut, Lebanon, and 2Sch, Akl, Elie; American University of Beirut,
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health policy, Public health
Keywords:	conflict of interest, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, health systems research

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Manuscript Title: Reporting of Conflicts of Interest by Authors of Primary Studies on Health Policy and Systems Research: a Cross-sectional Survey

Names and affiliations of all contributing authors:

Maram B. Hakoum¹ maram.hakoum@gmail.com, Lama Bou-Karroum² lb25@aub.edu.lb, Mounir Al-Gibbawi³ mounir.algibbawi@gmail.com, Assem M. Khamis¹ amk88@mail.aub.edu, Abdul Sattar Raslan³ anr06@mail.aub.edu, Sanaa Badour⁴ badoursa@hotmail.com, Arnav Agarwal^{5,6} arnav.agarwal@mail.utoronto.ca, Fadel Alturki³ fma46@mail.aub.edu, Gordon Guyatt⁶ guyatt@mcmaster.ca, Fadi El-Jardali^{6,7,8} fe08@aub.edu.lb, Elie A. Akl^{1,4,6} ea32@aub.edu.lb

¹ Clinical Research Institute, American University of Beirut Medical Center, Beirut, Lebanon

²Center for Systematic Reviews for Health Policy and Systems Research, American University of Beirut, Beirut, Lebanon

³ Faculty of Medicine, American University of Beirut, Beirut, Lebanon

⁴Department of Internal Medicine, American University of Beirut Medical Center, Lebanon

⁵Department of Medicine, University of Toronto, Toronto, Ontario, Canada

⁶Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada

⁷Knowledge to Policy (K2P) Center, Faculty of Health Sciences, American University of Beirut, Lebanon

⁸Department of Health Management and Policy, Faculty of Health Sciences, American University of Beirut, Lebanon

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Corresponding author:

Elie A. Akl, MD, MPH, PhD

Department of Internal Medicine

American University of Beirut Medical Center

P.O. Box: 11-0236

Riad-El-Solh Beirut 1107 2020

For peer review only

Abstract

Objectives: The objective of this study was to assess the frequency and types of conflict of interest (COI) disclosed by authors of primary studies of Health Policy and Systems Research (HPSR).

Design: We conducted a cross sectional survey using standard systematic review methodology for study selection and data extraction. We conducted descriptive analyses.

Setting: We collected data from papers published in 2016 in “health policy and service journals” category in Web of Science database.

Participants: We included primary studies (e.g., randomized controlled trials, cohort studies, qualitative studies) of HPSR published in English in 2016 peer-reviewed health policy and services journals.

Outcome measures: Reported COI disclosures including whether authors reported COI or not, form in which COI disclosures were provided, number of authors per paper that report any type of COI, number of authors per paper that report specific types and subtypes of COI.

Results: We included 200 eligible primary studies of which 132 (66%) included COI disclosure statements of authors. Of the 132 studies, 19 studies (14%) had at least one author reporting at least one type of COI and the most frequently reported type was individual financial COI (n=15, 11%). None of the authors reported individual intellectual COIs or personal COIs. Financial and individual COIs were reported more frequently compared with non-financial and institutional COIs.

Conclusion: A low percentage of HPSR primary studies included authors reporting COI. Non-financial or institutional COIs were the least reported types of COI.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Keywords: conflict of interest, health policy, health systems

Strengths and limitations of this study

- This is the first study to assess the frequency and types of COI disclosed by authors of primary studies of HPSR.
- The study used a rigorous methodology that included a search strategy specific to health policy and services journals and duplicate study selection and data abstraction processes.
- We used a comprehensive framework for the classification of COI.
- The study focused on reported COI, thus these statements depend on journals COI policy requirements, and whether authors’ disclosures are accurate or complete remains uncertain.

Background

Evidence-informed health policymaking aims to ensure that policymaking is well-informed by the best available evidence¹. Evidence from Health Policy and Systems Research (HPSR) can inform health system policy decisions including who delivers health services and where, and how these services are financed and organized^{2,3}. Furthermore, policymakers are increasingly recognizing the importance of the use of research evidence in improving health, reducing health inequities and contributing to economic development^{4,5}. However, conflict of interest (COI) of researchers may influence the conduct and reporting of HPSR.

COI is defined as “a financial or intellectual relationship that may impact an individual’s ability to approach a scientific question with an open mind”⁶. For instance, one study assessing the frequency and influence of financial COI on economic analyses in oncology found that the studies disclosing financial COI directly or indirectly consistently supported the sponsor’s product⁷. Additionally, Forsyth et al. found that opinion articles skeptical of the use of systematic reviews for policy-making were more likely to have industry ties than articles supportive of their use⁸.

Reporting of COI in HPSR is important given its potential influence on public policy and decision-making. We previously assessed the reporting of COI in HSPR systematic reviews⁹. We found that 20% of those reviews did not include a COI disclosure statement, and only 15% of disclosure statements reported the existence of any COI. Furthermore, the reporting of COI in primary studies is important for both policy makers,

relying on their findings for decision making, as well for authors of systematic reviews assessing the potential bias associated with the COI of study investigators ¹⁰. Therefore, this study aims to assess the types and frequency of COI disclosed by authors of primary studies of HPSR.

Methods

Design overview and definitions

We conducted a cross-sectional survey using standard systematic review methodology for study selection and data extraction. We defined COI disclosure as the reporting of whether a COI exists or not. We classified the types of disclosed COIs as shown in figure 1 and detailed in S1 appendix. Our classification of COIs relies on a framework informed by a literature review, the findings of recent studies assessing COIs reported by authors of clinical systematic reviews, HPSR systematic reviews and randomized controlled trials ^{9 11 12} and the International Committee of Medical Journal Editors (ICMJE) COI disclosure form¹³. We used the word “*loogly*” to label “*any additional statement in the COI disclosure that attempts to downplay a disclosed relationship by suggesting that it is unrelated to COP*” (e.g., ‘this relationship did not influence the content of the manuscript’) ¹¹.

Insert Figure 1 here

Figure 1: Classification of conflicts of interest

Eligibility criteria

We included articles meeting the following eligibility criteria:

- Type of study: primary studies (e.g., randomized controlled trials, cohort studies, qualitative studies). We excluded systematic and literature reviews, case studies, technical reports, conference reports, proceedings, editorials and opinion pieces; Type of field: health policy and systems research; we used the taxonomy of health systems topics used to code Health Systems Evidence (HSE) database of McMaster Health Forum to assess eligibility: governance, financial, delivery arrangements, and implementation strategies^{14 15}. Governance arrangements cover five topics: policy authority, organizational authority, commercial authority, professional authority, and consumer & stakeholder involvement. Financial arrangements include topics on financing systems, funding organizations, remuneration providers, purchasing products & services and incentivizing consumers. Delivery arrangements cover topics related to how care is designed to meet consumers' needs, by whom care is provided, where care is provided, with what supports is care provided. Implementation strategies comprise topics on consumer-targeted strategy, provider-targeted strategy and organization-targeted strategy.”
- Articles published in English in 2016.

Search strategy

We searched for papers published in peer-reviewed health policy and services journals. We ran the search in the Web of Science database limiting to “Health Policy and Services” journal category, “article” document type, English language and to the year 2016. S2 appendix presents the detailed search strategy.

Selection process

We drew a random sample of 200 papers from the set of citations retrieved by the search to undergo the selection process using an online random sequence generator (www.random.org/sequences). This sample of 200 primary studies is a subset of our previously published study on the reporting of funding in health policy and systems research¹⁶.

Citations were exported to EndNote™ X7.5 software (Thomson Reuters, Philadelphia, PA, USA). Reviewers completed calibration exercises before starting the selection process. Two reviewers screened title and abstracts for eligibility in duplicate and independently using EndNote. We ensured that papers retrieved by our search were effectively on HPSR. We retrieved the full text of citations judged as potentially eligible by at least one of the two reviewers. The two reviewers screened the full texts in duplicate and independently. The reviewers resolved their disagreements by discussion, and consulted a third reviewer when consensus could not be reached. We used a standardized and pilot tested full text screening form. We recorded reasons for exclusion and summarized the selection process results in a PRISMA study flow diagram¹⁷.

Data extraction process

We developed and pilot-tested a standardized data extraction form with detailed instructions (see S3 appendix). Two teams of eight reviewers completed calibration exercises and extracted data in duplicate and independently. Reviewers extracted study data using Research Electronic Data Capture (REDCap) tool, a secure, web-based

application designed to support data capture for research studies¹⁸. The reviewers compared results and resolved disagreements through discussion, or with the help of a third person when consensus could not be reached.

Extracted data

We extracted the following general characteristics of each article:

- Number of authors;
- Reported affiliation(s) of first and last author (private or public academic institution, government, not-for-profit organization, private-for-profit, intergovernmental);
- Country of affiliation of the first author and its classification (as per World Bank list of economies issued in September 2016);
- Health systems arrangement of the paper (governance, financial, delivery arrangements, and implementation strategies).

We extracted the following characteristics of the reported COI disclosures (as defined above):

- Whether authors reported COI or not;
- Form in which COI disclosures were provided (a narrative statement, an online document, available upon request);
- Number of authors per paper that report any type of COI;
- Number of authors per paper that report each specific type of COI, and when applicable, the different subtypes of COI;

- Whether the paper reports relevant characteristics of the COI (source, monetary value, duration);
- Whether individuals other than the authors provided COI disclosures (e.g. editors, peer-reviewers, external writers, others).

We extracted information the following information on the characteristics of the journal:

- Impact factor
- Existence of a COI disclosure policy

Data analysis

For eligible articles, we conducted descriptive analyses, focusing on the reported COI disclosures. For continuous variables, we present summary data as medians and quartiles since the application of the Kolmogorov– Smirnov (K–S) test did not demonstrate normality. We presented the results for categorical variables as frequencies and percentages, and analyzed them using the Chi-square test or, if the expected event number proved less than 5, the Fisher’s Exact test. We considered a p-value of < 0.05 as statistically significant. We performed the analysis using SPSS, version 21.0 for Windows (SPSS INC., Chicago, IL, USA).

Results

Out of the 2,648 citations identified, we included 200 eligible primary studies that were published in 55 “Health Policy & Services” journals. Figure 2 shows the study flow diagram.

Insert Figure 2

Figure 2: Study flow diagram

General characteristics of the included primary studies

Table 1 presents the general characteristics of the included primary studies. The median number of authors per study was four. The majority of studies were conducted by authors affiliated with institutions located in high-income countries (92%) where most articles were conducted in the United States (54%) followed by UK (8%). Most articles addressed the topic of delivery arrangements (72%). Most first authors and last authors were affiliated with public academic institutions (68% and 65% respectively).

Table 1: General characteristics of the included primary studies (N=200)

	Overall N (%)
Number of authors; Median (Interquartile range)	4 (3 – 6)
Classification of the country of the institution to which the first author is affiliated:	
<i>High income</i>	183 (92)
<i>United States</i>	107 (54)
<i>United Kingdom</i>	16 (8)
<i>Australia</i>	13 (7)
<i>Canada</i>	9 (5)
<i>The Netherlands</i>	7 (4)
<i>Other high income countries</i>	31 (16)
<i>Upper middle income</i>	10 (5)
<i>China</i>	3 (2)

<i>South Africa</i>	3 (2)
<i>Other upper middle income countries</i>	4 (2)
<i>Lower middle income</i>	4 (2)
<i>Kenya</i>	1 (0.5)
<i>Philippines</i>	1 (0.5)
<i>Bangladesh</i>	1 (0.5)
<i>Vietnam</i>	1 (0.5)
<i>Low income</i>	3 (2)
<i>Uganda</i>	3 (2)
Affiliation of first author *	
<i>Public academic institution</i>	135 (68)
<i>Private academic institution</i>	46 (23)
<i>Government</i>	18 (9)
<i>Not-for-profit organization</i>	23 (12)
<i>Private-for-profit</i>	2 (1)
<i>Intergovernmental</i>	1 (1)
Affiliation of last author *	
<i>Public academic institution</i>	129 (65)
<i>Private academic institution</i>	51 (26)
<i>Government</i>	21 (11)
<i>Not-for-profit organization</i>	20 (10)
<i>Private-for-profit</i>	3 (2)
<i>Intergovernmental</i>	0 (0)
Type of Health Systems Arrangement *	
<i>Delivery arrangement</i>	143 (72)
<i>Implementation strategies</i>	25 (13)
<i>Governance arrangement</i>	23 (12)
<i>Financial arrangement</i>	67 (34)

* Studies may have more than one option that applies.

Characteristics of the reported COI disclosures

Of the 200 primary studies, 66% (132/200) included COI disclosure statements of authors. All but one study provided COI disclosures narratively in the main document; the single study provided them in an online form that was not accessible. None of the included studies reported COI by individuals other than the authors (e.g. editors or peer-reviewers).

Table 2 presents the reporting of the different types of COI in the 132 studies that included COI disclosure statements. Of these 132 studies that included COI disclosure statements, 19 (14%) had at least one author reporting at least one type of COI while 113 (86%) studies had their authors reporting that they had no conflict of interest. The most frequently reported type was individual financial COI (n=15, 11%), with the median percentage of authors reporting this type of COI being 25%. None of the authors reported individual intellectual COIs or personal COIs. Of the 132 primary studies that provided COI disclosure statements, more had at least one author reporting financial COIs compared to non-financial COIs (n=16; 12% versus n=3; 2%; p-value=0.04). More studies had at least one author reporting individual COIs compared to institutional COIs (n=15; 11% versus n=5; 4%; p-value=0.01).

Table 2: Reporting by primary study authors of the different types of conflict of interest (COI) (N=132)

	Studies with at least one author reporting a specific type of COI *; n (%)	Distribution of the percentage of authors per study reporting that type of COI §;
--	---	---

		Median (Interquartile range)
At least one type	19 (14)	25 (17 – 50)
Individual financial (direct benefit)	15 (11)	25 (15 – 50)
Individual financial (benefit through professional status)	0 (0)	N/A
Individual intellectual	0 (0)	N/A
Individual personal	0 (0)	N/A
Institutional financial	2 (2)	a
Institutional intellectual	3 (2)	b
Institutional cultural	0 (0)	N/A
“Other types” §	4 (3)	30 (18 – 85)
Provided a “loogly statement”	3 (2)	c

* One study can have authors reporting more than one type of COI.

§ Calculated using the number of papers with at least one author reporting the specific type of COI (i.e., papers counted in the preceding column) as the denominator.

§ “Other types” of COIs included: ‘implementing national clinical audit’ (n=1), ‘non-compensated affiliations’ (n=1), ‘attended meetings’ (n=1), and relationship with a publishing entity (n=1). We consider these as individual and non-financial types of COI.

^a Authors of only 2 studies reported institutional financial COI, with the percentages being 20% and 100%.

^b Authors of only 3 studies reported institutional intellectual COI, with the percentages being 20%, 25%, and 33%.

^c Authors of only 3 studies provided a “loogly statement”, with the percentages being 10%, 25% and 100%.

N/A=Not applicable

Individual financial COI: Table 3 presents the reporting of the different subtypes of individual financial COI in the 15 primary studies with at least one author reporting

individual financial COI. The two most frequently reported subtypes were ‘personal fees’ (n=9; 60%) and ‘grant’ (n=6, 40%). The median percentages of authors reporting these two subtypes were 20% and 18% respectively.

Table 3: Reporting of primary study authors of different subtypes of individual financial conflict of interest (COI) (N=15)

	Studies with at least one author reporting the subtype of individual financial COI *; n (%)	Distributions of the percentage of authors per study reporting that subtype of COI §; Median (Interquartile range)
Grant	6 (40)	18 (9 – 27)
Employment	2 (13)	^a
Personal fees (other than employment)	9 (60)	20 (12 – 38)
Non-monetary support	1 (7)	^b
Study supplies/services	0 (0)	N/A
Patent(s)	0 (0)	N/A
Stocks, bonds, stock options, other securities	3 (20)	^c
“Other subtypes”	0 (0)	N/A

* One study can have authors reporting more than one type of COI.

§ Calculated using the number of papers with at least one author reporting the specific type of COI (i.e., papers counted in the preceding column) as the denominator.

^a Authors of only 2 studies reported “Employment”, with the percentages being 50% and 100%.

^b Authors of only 1 study reported “Non-monetary support”, with the percentage being 17%.

^c Authors of only 3 studies reported “Stocks, bonds, stock options, other securities”, with the percentages being 20%, 25% and 33%.
N/A=Not applicable

Of the 15 studies with at least one author reporting individual financial COI, 14 reported the source of financial COI. Only two of these 14 studies specified the relationship of the source to the field under study; in both cases, the sources produced a product not the subject of the study but under the same field. Only one of the 15 studies reported on the timing of the conflicted relationship relative to the conduct of the study; in that case, the relationship occurred during the conduct of the study. None of the studies reported on the monetary value of the financial COI.

Characteristics of the Journals

The median impact factor of the 55 journals that published the included primary studies was 1.66 (IQR=1.36-2.41). Ninety-six percent (53/55) of the journals had a COI disclosure policy requiring authors to report their conflict of interests. Of the 68 papers that did not include a COI statement, 90% (61/68) were published in journals that did have a COI disclosure policy. The percentage of papers that included a COI statement was 68.2% in journals with a COI disclosure policy and 12.5% in journals without a COI disclosure policy (p=0.012). We provided the list of the 55 journals that published the included primary studies in S4 appendix.

Discussion

Summary of findings

In summary, 66% of 200 HPSR primary studies included COI disclosure statements of authors, with only one using an inaccessible online disclosure form. Of these studies,

14% had at least one author reporting at least one type of COI. Most frequently, authors reported individual financial COI. Very few studies reported non-financial or institutional COIs. The two most frequently reported subtypes of individual financial COI were 'personal fees' and 'grant'. None of the studies reported on the monetary value of the financial COI, or provided disclosure by individuals other than the authors such as editors or reviewers.

Strengths and limitations

This is the first study to assess the frequency and types of COI disclosed by authors of primary studies of HPSR. We have used a rigorous methodology that included a search strategy specific to health policy and services journals and duplicate study selection and data abstraction processes. We used a comprehensive framework for the classification of COI used in previous studies^{9 11 12}. Our study focused on reported COI, thus these statements depend on journals COI policy requirements, and whether authors' disclosures are accurate or complete remains uncertain.

Comparison to other studies

Our findings, in relation to similar studies, demonstrate that COI disclosure statements are less frequently included in HPSR primary studies (66%) compared to HPSR systematic reviews (80%), clinical randomized controlled trials (94%), and clinical systematic reviews (97%) (figure 3)^{9 11 12}. Factors that may be contributing to these differences include the less rigorous COI policies in HPSR journals compared to Core Clinical journals, and potentially a less strict implementation: 93% of HPSR journals

(including the 55 journals that published the primary studies included in this study) have a COI disclosure policy compared to 99% for Core Clinical journals ^{19 20}.

The percentage of authors reporting any type of COI in HPSR primary studies (14%) was comparable to that of HPSR systematic reviews (15%). However, that percentage is much lower compared to that of clinical systematic reviews (41%) and clinical trials (57%) ^{9 11}

¹². *“Possible explanations for this low rate of disclosure could be either an actual low prevalence of COI in this field, or an underreporting by HPSR authors of their COIs..*

Indeed, an increasing number of studies is using resources such as the Open Payment database to verify the accuracy of the COI disclosures of health researchers ²¹⁻²⁴. They are consistently showing that researchers tend to underreport their conflicts of interest (up to 81% in one study ²⁵).

Reporting of financial COI was higher than non-financial COI in HPSR primary studies. This is consistent with the findings of previous studies that focused on COI reporting in HPSR systematic reviews, clinical systematic reviews, and randomized controlled trials ^{9 11 12}. Although this might reflect how frequently these types of COI exist, it might also be that authors are less aware of the concept of non-financial COI, or of what exactly qualifies as a non-financial COI. Another explanation could be related to the extent of use of standard COI disclosure forms: we found that only one study used a standardized form to report COI, compared to 12% in clinical trials ¹².

Insert Figure 3 here

Figure 3: chart comparing the reporting of financial and non-financial COI in different types of publications. The denominator for the reporting of the different types of COI is the number of studies that included a COI disclosure statement.

Implications for practice and research

As HPSR may be used to inform policy decisions, COI of HPSR authors may bias their research output and subsequently lead to misguided public policies and decisions^{26 27}. For example, Bes-Rastrollo et al. found that financial COI may bias findings of systematic reviews of the effects of sugar-sweetened beverages consumption on weight gain and obesity²⁸. In turn, such biased conclusions might adversely influence policymaking related to regulation of sugar-sweetened beverages. Consequently, the appropriate disclosure and management of COIs are essential for the credibility and trust in HPSR and hence, might increase its uptake in policymaking. For that reason, HPSR journals to strengthen their COI disclosure policies, and the implementation of existing policies. One approach to help authors better recognize and disclose their COIs would be to develop a standardized COI disclosure form similar to that of the ICMJE but more specific to health policy and systems research. Journals publishing HPSR should also consider collecting and publishing the COIs of editors and peer-reviewers. Future research should investigate the reasons behind the higher reporting of financial COI compared with non-financial COI in HPSR primary studies. Investigate of the accuracy and completeness of reporting of COI may also provide insight into the low rates of disclosed COI.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Contributions: MBH, LBK, FEJ, GG, and EAA conceived and designed the study. MBH coordinated the study throughout. EAA had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. MBH and LBK ran the search and study selection processes. MBH, LBK, MAG, AK, ASR, SB, AA, and FA extracted the data. MBH, LBK, and EAA analyzed and interpreted the data. MBH and LBK wrote the first draft of the manuscript with EAA. All authors critically revised the manuscript and approved the final version. The lead author EAA affirms that this manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Funding: This work was supported by the American University of Beirut Faculty of Medicine’s Medical Practice Plan (MPP) funds.

Acknowledgements: None

Competing interests: Maram B. Hakoum, Gordon Guyatt, and Elie A. Akl have competing interests related to their research in the area of conflicts of interest.

Ethics approval: The study involves no human subjects and requires no ethical approval.

Patient and Public Involvement: It was not appropriate or possible to involve patients or the public in this work.

Data sharing statement: All data relevant to the study are included in the article or uploaded as supplementary information.

References

1. Oxman AD, Lavis JN, Lewin S, et al. SUPPORT Tools for evidence-informed health Policymaking (STP) 1: What is evidence-informed policymaking? *Health research policy and systems* 2009;7 Suppl 1:S1. doi: 10.1186/1478-4505-7-s1-s1 [published Online First: 2009/12/19]
2. Gilson L, Hanson K, Sheikh K, et al. Building the Field of Health Policy and Systems Research: Social Science Matters. *PLoS Medicine* 2011;8(8):e1001079. doi: 10.1371/journal.pmed.1001079
3. Koon AD, Rao KD, Tran NT, et al. Embedding health policy and systems research into decision-making processes in low- and middle-income countries. *Health research policy and systems* 2013;11(1):30. doi: 10.1186/1478-4505-11-30
4. Lavis JN, Posada FB, Haines A, et al. Use of research to inform public policymaking. *The Lancet*;364(9445):1615-21. doi: 10.1016/S0140-6736(04)17317-0
5. El-Jardali F, Lavis JN, Ataya N, et al. Use of health systems evidence by policymakers in eastern mediterranean countries: views, practices, and contextual influences. *BMC Health Services Research* 2012;12(1):200. doi: 10.1186/1472-6963-12-200
6. Schunemann HJ, Osborne M, Moss J, et al. An official American Thoracic Society Policy statement: managing conflict of interest in professional societies. *American journal of respiratory and critical care medicine* 2009;180(6):564-80. doi: 10.1164/rccm.200901-0126ST
7. Jang S, Chae YK, Majhail NS. Financial Conflicts of Interest in Economic Analyses in Oncology. *American Journal of Clinical Oncology* 2011;34(5):524-28. doi: 10.1097/COC.0b013e3181f4799b
8. Forsyth SR, Odierna DH, Krauth D, et al. Conflicts of interest and critiques of the use of systematic reviews in policymaking: an analysis of opinion articles. *Systematic reviews* 2014;3:122. doi: 10.1186/2046-4053-3-122 [published Online First: 2014/11/25]
9. Bou-Karroum L, Hakoum MB, Hammoud MZ, et al. Reporting of Financial and Non-financial Conflicts of Interest in Systematic Reviews on Health Policy and Systems Research: A Cross Sectional Survey. *International journal of health policy and management* 2018;7(8):711-17. doi: 10.15171/ijhpm.2017.146
10. Elia N, von Elm E, Chatagner A, et al. How do authors of systematic reviews deal with research malpractice and misconduct in original studies? A cross-sectional analysis of systematic reviews and survey of their authors. *BMJ Open* 2016;6(3):e010442. doi: 10.1136/bmjopen-2015-010442
11. Hakoum MB, Anouti S, Al-Gibbawi M, et al. Reporting of financial and non-financial conflicts of interest by authors of systematic reviews: a methodological survey. *BMJ Open* 2016;6(8):e011997. doi: 10.1136/bmjopen-2016-011997
12. Hakoum MB, Jouni N, Abou-Jaoude EA, et al. Authors of Clinical Trials Reported Individual and Financial Conflicts of Interest More Frequently than Institutional and non-financial Ones: a Methodological Survey. *J Clin Epidemiol* 2017 doi: 10.1016/j.jclinepi.2017.04.002

13. Gallagher SS. Characteristics of evaluated childhood agricultural safety interventions. *Journal of agromedicine* 2012;17(2):109-26. doi: 10.1080/1059924x.2012.664033 [published Online First: 2012/04/12]

14. Kendrick D, Barlow J, Hampshire A, et al. Parenting interventions and the prevention of unintentional injuries in childhood: systematic review and meta-analysis. *Child: care, health and development* 2008;34(5):682-95. doi: 10.1111/j.1365-2214.2008.00849.x [published Online First: 2008/09/18]

15. Lavis JN, Wilson MG, Moat KA, et al. Developing and refining the methods for a 'one-stop shop' for research evidence about health systems. *Health research policy and systems* 2015;13:10. doi: 10.1186/1478-4505-13-10 [published Online First: 2015/05/15]

16. Khamis AM, Bou-Karroum L, Hakoum MB, et al. The reporting of funding in health policy and systems research: a cross-sectional study. *Health Res Policy Syst* 2018;16(1):83-83. doi: 10.1186/s12961-018-0356-3

17. Moher D, Liberati A, Tetzlaff J, et al. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med* 2009;6(7):e1000097. doi: 10.1371/journal.pmed.1000097 [published Online First: 2009/07/22]

18. Harris PA, Taylor R, Thielke R, et al. Research Electronic Data Capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of biomedical informatics* 2009;42(2):377-81. doi: 10.1016/j.jbi.2008.08.010

19. Khamis AM, Hakoum MB, Bou-Karroum L, et al. Requirements of health policy and services journals for authors to disclose financial and non-financial conflicts of interest: a cross-sectional study. *Health research policy and systems* 2017;15(1):80. doi: 10.1186/s12961-017-0244-2

20. Shawwa K, Kallas R, Koujanian S, et al. Requirements of Clinical Journals for Authors' Disclosure of Financial and Non-Financial Conflicts of Interest: A Cross Sectional Study. *PLoS ONE* 2016;11(3):e0152301. doi: 10.1371/journal.pone.0152301

21. Boddapati V, Fu MC, Nwachukwu BU, et al. Accuracy Between AJSM Author-Reported Disclosures and the Centers for Medicare and Medicaid Services Open Payments Database. *The American journal of sports medicine* 2018;46(4):969-76. doi: 10.1177/0363546517750124 [published Online First: 2018/02/01]

22. Cherla DV, Viso CP, Olavarria OA, et al. The Impact of Financial Conflict of Interest on Surgical Research: An Observational Study of Published Manuscripts. *World Journal of Surgery* 2018;42(9):2757-62. doi: 10.1007/s00268-018-4532-y

23. Jimbo M, Granberg CF, Osumah TS, et al. Discrepancies in Self-Reported and Actual Conflicts of Interest for Robotic Pediatric Urological Surgery. *The Journal of urology* 2019;201(2):393-99. doi: 10.1016/j.juro.2018.07.043 [published Online First: 2018/07/28]

24. Luce EA, Jackman CA. Disclosure of Financial Conflicts of Interest in Plastic and Reconstructive Surgery. *Plastic and reconstructive surgery* 2017;140(3):635-

39. doi: 10.1097/prs.0000000000003598 [published Online First: 2017/08/26]
25. Patel SV, Yu D, Elsolh B, et al. Assessment of Conflicts of Interest in Robotic Surgical Studies: Validating Author's Declarations With the Open Payments Database. *Annals of surgery* 2018;268(1):86-92. doi: 10.1097/sla.0000000000002420 [published Online First: 2017/07/13]
26. Mandrioli D, Kearns CE, Bero LA. Relationship between Research Outcomes and Risk of Bias, Study Sponsorship, and Author Financial Conflicts of Interest in Reviews of the Effects of Artificially Sweetened Beverages on Weight Outcomes: A Systematic Review of Reviews. *PLOS ONE* 2016;11(9):e0162198. doi: 10.1371/journal.pone.0162198
27. Scollo M, Lal A, Hyland A, et al. Review of the quality of studies on the economic effects of smoke-free policies on the hospitality industry. *Tobacco Control* 2003;12(1):13-20. doi: 10.1136/tc.12.1.13
28. Bes-Rastrollo M, Schulze MB, Ruiz-Canela M, et al. Financial conflicts of interest and reporting bias regarding the association between sugar-sweetened beverages and weight gain: a systematic review of systematic reviews. *PLoS medicine* 2013;10(12):e1001578-e78. doi: 10.1371/journal.pmed.1001578 [published Online First: 12/31]

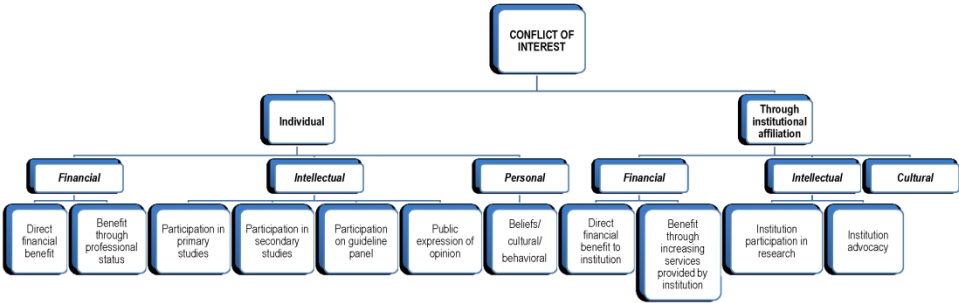


Figure 1: Classification of conflicts of interest

240x130mm (300 x 300 DPI)

2,648 records identified
by the search strategy
(search run on 11/07/2016)

500 records randomly sampled

500 titles and abstracts
assessed for eligibility

257 records excluded

243 full-text papers
assessed for eligibility

43 records excluded
38 not identified as
primary studies
5 not on HPSR

200 papers included

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

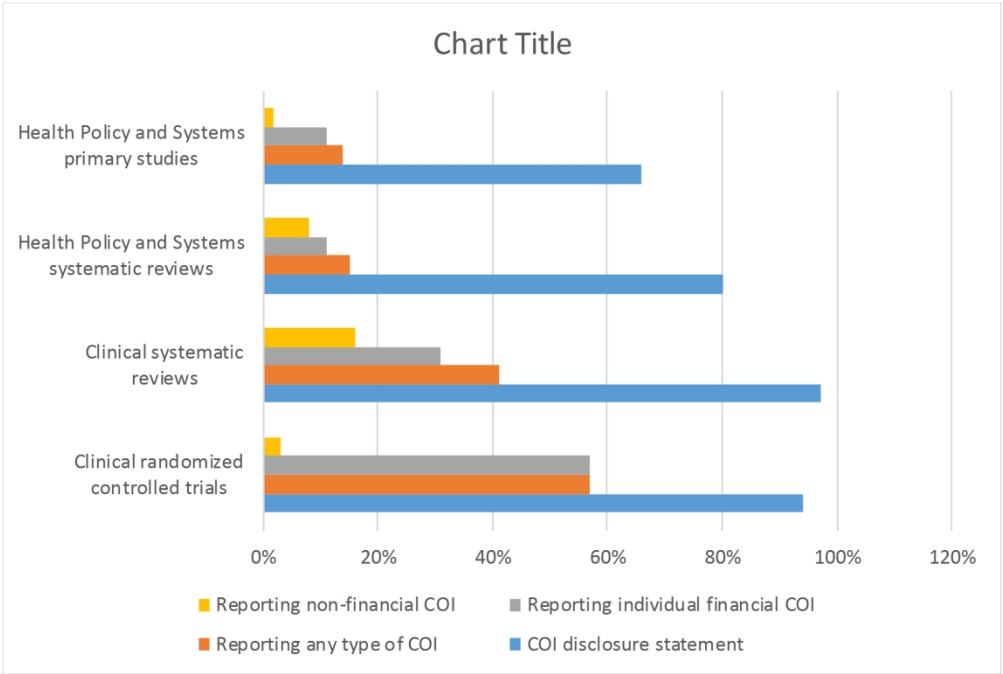


Figure 3: chart comparing the reporting of financial and non-financial COI in different types of publications. The denominator for the reporting of the different types of COI is the number of studies that included a COI disclosure statement.

198x133mm (300 x 300 DPI)

S1 Appendix: Classification of conflicts of interest

Conflicts of interest can be individual or exist through institutional affiliations:

- Individual COIs. Types of individual COI include financial, intellectual and personal COIs.
- Types of institutional COI include financial, intellectual and cultural COIs.

Part 1: Classification of individual financial COI

Part 1a: Individual financial COI with direct financial benefit

Definition:

Individual financial COI with direct financial benefit arises from any payment, research funding, consultancy, advisory board membership, and the like from the manufacturer of a drug or device or service under consideration. This type of COI may involve the individuals themselves, their families or a business they own. Typically, a timeframe of three to five years is considered for these COIs.

Grant

There could be a differentiation whether the grant is going to the investigator or to his/her institution. Types: grant; salary for research; contract; fellowship; unrestricted educational funding; peer-reviewed grant funding

Employment

Types: former employment; current employment; stipend; salary

Personal fees (other than employment)

Types: honoraria, royalties, fees for consulting, lectures, speakers' bureaus, expert testimony, presentations, editorial work, manuscript preparation, trial involvement, management, educational support, production of books, article research, scientific meetings, entertainment, gift, charitable contribution, other affiliations (e.g. advisory board, steering committee membership, supported by another party for holding a chair at one's institution)

Non-monetary support	<i>Types: travel paid; writing assistance; administrative support; food and beverage</i>
Study supplies/services	
Patent(s)	
Stocks, bonds, stock options, other securities (e.g. equity)	
Other forms	

Part 1b: Individual financial COI with benefit through professional status

Definition: Individual financial COI with benefit through professional status arises when an individual is "engaged in a specified activity as one's main paid occupation" or "a member of a professional group of individuals".
<i>e.g. an author that is a dietician conducts a study looking at advice vs. no advice from a dietician; an author that provides colonoscopy services; an author that works at a warfarin clinic</i>

Part 2: Classification of individual intellectual COI

Definition: Individual intellectual COI arises when an individual participates in scholarly activities related to the issue under consideration, or when an individual has taken a position or has an opinion and expresses it in a statement publicly. Such activities may result in an emotional attachment to a particular interpretation of evidence or position regarding optimal course of action.	
Participation in primary studies	<i>e.g. randomized controlled trials; case-control studies, observational studies, qualitative studies</i>
Participation in secondary studies	<i>e.g. systematic reviews</i>
Participation on guideline panel	<i>e.g. Chair of American Heart Association Get With The Guidelines Steering Committee</i>

Public expression of opinion	<i>e.g. textbook; review article; editorial; presentation</i>
------------------------------	---

Part 3: Classification of individual personal COI

Definition:

when an individual has personal opinions or conditions that concern one's private life, relationships, and emotions rather than one's career or public life.

Beliefs (religious, political, philosophical)	<i>e.g. an author against organ donation or abortion attributed to personal religious beliefs</i>
---	---

Personal characteristics (gender, age, race, physical/psychiatric condition, sexual orientation)	<i>e.g. an author with a physical disability conducting a study on the benefit of physical rehabilitation</i>
--	---

Part 4: Classification of institutional financial COI

Part 4a: Institutional financial COI with direct financial benefit to the institution

Definition:

Institutional financial COI arises when an institution, to which an individual belongs, has a relationship with the manufacturer of a drug or device or service under consideration. Such institutions include academic medical centers and professional societies.

Seeking and receiving gifts, endowments, or grants from companies, for example, a gift of an endowed university chair

Types: grants for research/fellowship/salary support; merit awards; endowments; patent funds; educational fees; funds for author activities (speaker fee, consultancy, honoraria, board membership, testimony, writing); funds for drug/equipment supplies

Conduct of research within the institution that relates to the issue under consideration and could affect the value of the institution's patents or its equity positions or options in biotechnology, pharmaceutical, or medical device companies

Senior officials who act on behalf of the institution have personal financial interests related to the issue under consideration

Part 4b: Institutional financial COI with benefit through increasing services provided by the institution

Definition:
when an institution employs professionals who advocate for clinical services related to the issue under consideration but don't provide those services themselves.

Part 5: Classification of institutional intellectual COI

Definition: Institutional intellectual COI arises when an institution/organization, to which an individual belongs, focuses or funds research on a specific topic, or arises when an individual (paid employee or unpaid member) belongs to an institution/organization that clearly advocates for the issue under consideration.	
Institution participation in research	<i>e.g. an author works at a hospital which is enrolling participants in a trial on a certain topic; an author is a member of an organization that has a research focus on a certain topic</i>
Institution advocacy when the institution:	<div><div>1.</div><div>is an advocacy group that clearly advocates for the issue under consideration</div></div> <div><div>2.</div><div>has advocacy related to the issue under consideration as part of its mission, objectives, work, or stated position (i.e. position statement, editorial, blog, amicus brief, or legislature or legal testimony)</div></div> <div><div>3.</div><div>shows "public support for or recommendation of a particular cause or policy"</div></div> <div><div>4.</div><div>has senior officials who act on its behalf and have COI related to the issue under consideration</div></div>

Part 6: Classification of institutional cultural COI

Definition:

Institutional cultural COI arises when an individual (paid employee or unpaid member) belongs to an institution/organization that has a specific cultural identity (e.g. catholic university).

For peer review only

S2 Appendix: Search strategy

Web of Science search strategy for health policy and services papers

1. Advanced search for “WC=(Health Policy & Services)”
2. Limit to “English”
3. Refine document types to “article”
4. Limit time span to: “01/01/2016 to present”
5. Select Social Sciences Citation Index

Data Abstraction Form (COI in HPS studies)

Record Number

Last name of the First Author

Study Title

Journal number

1- Please select your name below

1.A- Reviewer name

- ☐ Abdul Sattar
☐ Arnav
☐ Assem
☐ Lama
☐ Maram
☐ Mounir
☐ Sanaa
☐ Fadel

2- General characteristics of the study

2.A.1- Number of authors

2.A.2a- Please select the reported affiliation(s) by the FIRST author

- ☐ Private academic/university
☐ Public academic/university
☐ Government
☐ Not for profit organization
☐ Private for profit
☐ Intergovernmental

2.A.2b- Please select the reported affiliation(s) by the LAST author

- ☐ Private academic/university
☐ Public academic/university
☐ Government
☐ Not for profit organization
☐ Private for profit
☐ Intergovernmental

2.B.1- Please insert the Country of the affiliation of the first author:

2.B.2- Country classification (please see Supplementary File):

- ☐ High income
☐ Upper-middle income
☐ Lower-middle income
☐ Low income

3- Funding of the study

3.A- Is the study funded?

- ☐ Funded
☐ Not funded
☐ Not reported

3.B- Reported Source(s) of Funding/Support (check all that apply)

- ☐ 1. Internally funded
☐ 2. Governmental
☐ 3. Private for Profit
☐ 4. Private not for Profit with evidence of support by Private for Profit that is a Drug/Device Industry
☐ 5. Private not for Profit with evidence of support by Private for Profit that is NOT a Drug/Device Industry
☐ 6. Private not for Profit with no evidence of support by Private for Profit
☐ 7. Intergovernment
(Note: 1 for Internal sources of funding; 2-6 for External sources of funding)

3.C.1a- Does the paper explicitly report whether the funder/sponsor was involved in the following?

	Not involved	Involved	Not reported
1. Protocol/design of the study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Data collection	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Data analysis/ interpretation/ management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Funded a writer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Preparation of the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Review of the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Approval of the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Decision to submit the manuscript	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Verified data accuracy/fact checking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Auditing of study conduct	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Conduct of study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Study oversight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Logistical support	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Team assembly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Other (please specify below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3.C.1b- If other, please specify

4- Conflict of Interest Disclosure

4.A- Does the paper report COI in the following forms? (check all that apply)

- ☐ Yes, narrative statement in the main document
☐ Yes, in an online document (accessible)
☐ Yes, in an online document (not accessible)
☐ Yes, available upon request
☐ No

4.A.1- Please copy and paste the quotation declaring COI from the main document

1 4.B.1a- The online document reports COI as (check all
2 that apply):

- ☐ Narrative statement
☐ ICMJE Uniform Disclosure Form
☐ Other form

3
4 4.B.1b- If other form, please specify _____
5

6 4.B.2- Please copy and paste the quotation declaring
7 COI from the online document _____
8

9 4.C.1- How many authors report any type of COI in the
10 Main document? _____
11

12 4.C.2- How many authors report any type of COI in the
13 Online document? _____
14
15

16 **4.D- For how many authors:**

17
18
19 4.D.1- Does the online document report more
20 disclosures than the main document? _____
21

22 4.D.2- Does the online document report less
23 disclosures than the main document? _____
24

25 4.D.3- Does the online document report the same
26 disclosure(s) as in the main document? _____
27

28 4.D.4- Does the online document report more details
29 than the main document for the same disclosure(s)? _____
30

31 4.D.5- Does the online document report less details
32 than the main document for the same disclosure(s)? _____
33
34

35 **5- Disclosure(s) of Individual Financial COI (with direct financial benefit)**

36
37
38 5.A- How many authors report COI related to any
39 subtype of individual financial COI (with direct
40 financial benefit)? _____
41
42

43 **5.B- If any individual financial COI is reported, for how many authors does it relate to the** 44 **following subtypes?**

45
46
47 5.B.1- Grant from source(s) same as funding source(s) _____
48

49 5.B.2a- Grant from source(s) different from funding
50 source(s) _____
51

52 5.B.2b- Please specify the source(s) that are
53 different from the funding source(s): _____
54

55 5.B.3- Employment _____
56

57 5.B.4- Personal fees (other than Employment) _____
58

59 5.B.5- Non-monetary support _____
60

5.B.6- Drug/Equipment supplies _____

5.B.7a- Patent(s) _____

Yes

No

☐☐

5.B.7b.1- Does the disclosure specify whether a patent relates to one of the interventions subject of the study?

☐☐

5.B.7b.2- Does the disclosure specify whether a interventions relates to the field but not any of the interventions subject of the study?

5.B.8- Stocks, bonds, stock options, other securities

5.B.9a- Other forms

5.B.9b- If other, please specify here:

5.C- Does the disclosure include the following?

5.C.1a- Source(s)

☐ Yes☐ No

5.C.1b- Does the paper specify whether:

5.C.1b.1- Any source(s) of COI produces one of the interventions subject of the study?

Yes

☐

No

☐

5.C.1b.2- Any source(s) of COI produces interventions not subject of the study but under the same field?

☐☐

5.C.2a- Monetary value

☐ Yes☐ No

5.C.2b- If monetary value is specified, please copy and paste the quotation here:

5.C.3a- Time period

☐ Yes☐ No

5.C.3b- If time period is specified, please select longest duration reported:

☐ During conduct of the study☐ 1 year☐ 2 years☐ 3 years☐ 4 years☐ 5 years☐ >5 years

6- Disclosure(s) of Individual Financial COI (with benefit through professional status)

6.A- How many authors report COI related to any subtype of individual financial COI (with benefit from professional status)? _____

6.B- Does the disclosure specify whether:

Yes

No

6.B.1- Any type(s) of Individual Financial COI (with benefit through professional status) relates to one of the interventions subject of the study?

☐☐

6.B.2- Any type(s) of Individual Financial COI (with benefit through professional status) relates to interventions not subject of the study but under the same field?

☐☐

7- Individual Intellectual COI Disclosure(s)

7.A- How many authors report on the following subtypes of Individual Intellectual COI?

7.A.1- Participation in primary studies _____

7.A.2- Participation in secondary studies _____

7.A.3- Participation in guideline panel(s) _____

7.A.4- Public expression of opinion _____

7.B- Does the disclosure specify whether:

Yes

No

7.B.1- Any type(s) of Individual Intellectual COI relates to one of the interventions subject of the study?

☐☐

7.B.2- Any type(s) of Individual Intellectual COI relates to interventions not subject of the study but under the same field?

☐☐

8- Individual Personal COI Disclosure(s)

8.A.1- How many authors report Individual Personal COI in any form? _____

8.A.2- If any form of Individual Personal COI is disclosed by any author, please copy and paste the quotation(s) here: _____

8.B- Does the disclosure specify whether:

Yes

No

8.B.1- Any type(s) of Individual Personal COI relates to one of the interventions subject of the study?

☐☐

8.B.2- Any type(s) of Individual Personal COI relates to interventions not subject of the study but under the same field?

☐☐

9- Institutional Financial COI Disclosure(s)

9.A.1- How many authors report Institutional Financial COI, with direct financial benefit to the institution? _____

9.A.2- How many authors report Institutional Financial COI, with benefit through increasing services provided by institution? _____

9.A.3- If any form of Institutional Financial COI is disclosed by any author, please copy and paste the quotation(s) here: _____

9.B- Does the disclosure include the following?

9.B.1a- Source(s)

☐ Yes☐ No

9.B.1b- Does the paper specify whether:

Yes

No

9.B.1b.1- Any source(s) of COI produces one of the interventions subject of the study?

☐☐

9.B.1b.2- Any source(s) of COI produces interventions not subject of the study but under the same field?

☐☐

9.B.2a- Monetary value

☐ Yes☐ No

9.B.2b- If monetary value is specified, please copy and paste the quotation here:

9.B.3a- Time period

☐ Yes☐ No

9.B.3b- If time period is specified, please select longest duration reported:

☐ During conduct of the study☐ 1 year☐ 2 years☐ 3 years☐ 4 years☐ 5 years☐ >5 years

10- Institutional Intellectual COI Disclosure(s)

10.A.1- How many authors report Institutional Intellectual COI related to institution participation in research?

10.A.2- How many authors report Institutional Intellectual COI related to institution advocacy?

10.A.3- If any form of Institutional Intellectual COI is disclosed by any author, please copy and paste the quotation(s) here:

10.B- Does the disclosure specify whether:

Yes

No

10.B.1- Any type(s) of Institutional Intellectual COI relates to one of the interventions subject of the study?

☐☐

1 10.B.2- Any type(s) of
2 Institutional Intellectual COI
3 relates to interventions not
4 subject of the study but under
5 the same field?
6
7
8
9

☐☐

11- Institutional Cultural COI Disclosure(s)

12 11.A.1- How many authors report Institutional
13 Cultural COI? _____
14

15 11.A.2- If any form of Institutional Cultural COI is
16 disclosed by any author, please copy and paste the
17 quotation(s) here: _____
18
19

11.B- Does the disclosure specify whether:

24 11.B.1- Any type(s) of
25 Institutional Cultural COI relates
26 to one of the interventions
27 subject of the study?
28
29

Yes

☐

No

☐

31 11.B.2- Any type(s) of
32 Institutional Cultural COI relates
33 to interventions not subject of
34 the study but under the same
35 field?
36
37
38

☐☐

12- Other COI Disclosure(s)

42 12.A- For COI disclosures that you could not
43 categorize, please specify the number of authors
44 (eg. 5 authors) for the uncategorized disclosures
45 then copy/paste the statement(s) here: _____
46
47

13- Non-Influential/Unrelated COI Disclosures

51 13.A- For COI disclosures that describe a
52 relationship (e.g., payment from drug company) then
53 include the loogly statement such as "this was
54 unrelated to the subject" or "but she did not
55 endorse..." or "this relationship did not influence
56 his decision": Please specify the number of authors
57 that include such a statement (eg, 5 authors) then
58 copy/paste the statement(s) here: _____
59
60

14- COI Disclosures by Individuals other than the authors

14.A- For Editor(s): is there a reference to a COI disclosure statement (available in the full-text, or as an accessible ICMJE form, or upon request)?

☐ Yes
☐ No

14.B- For Peer-reviewer(s): is there a reference to a COI disclosure statement (available in the full-text, or as an accessible ICMJE form, or upon request)?

☐ Yes
☐ No

14.C.1a- Does the paper report contribution by an external writer?

☐ Yes
☐ No

14.C.1b- If yes, is there a reference to a COI disclosure statement (available in the full-text, or as an accessible ICMJE form, or upon request) by the external writer?

☐ Yes
☐ No

14.D.1a- Does the paper provide COI disclosures by other individuals/groups (besides the authors, editors, peer-reviewers, external writers)?

☐ Yes
☐ No

14.D.1b- If yes, please copy/paste the statements here:

15- Requested COI Disclosures

Please skip this section (only for Maram to fill)

15.A- Was information on COI provided upon request?

☐ Yes
☐ No

15.B.1a- The provided document reports COI as (check all that apply):

☐ Narrative statement
☐ ICMJE Uniform Disclosure Form
☐ Other form

15.B.1b- If other form, please specify

15.C- For how many authors:

15.C.1- Does the provided document report more disclosures than the main document?

15.C.2- Does the provided document report less disclosures than the main document?

15.C.3- Does the provided document report the same disclosure(s) as in the main document?

15.C.4- Does the provided document report more details than the main document for the same disclosure(s)?

15.C.5- Does the provided document report less details than the main document for the same disclosure(s)?

S4 Appendix: List of 55 journals publishing the included primary studies

Health Affairs
BMJ Quality & Safety
Health Expectations
Implementation Science
Medical Care
Milbank Quarterly
Health Services Research
Medical Care Research And Review
Pharmacoeconomics
International Journal For Quality In Health Care
Health Policy And Planning
Administration and Policy in Mental Health and Mental Health Services Research
Quality Of Life Research
Human Resources for Health
Journal Of Health Economics
Psychiatric Services
European Journal Of Health Economics
Palliative & Supportive Care
Patient-Patient Centered Outcomes Research
Health And Quality Of Life Outcomes
Health Economics
Health Promotion International
Health Policy
Psychology Public Policy And Law
AIDS Care-Psychological And Socio-Medical Aspects Of AIDS/HIV
Journal of Health Services Research & Policy
BMC Palliative Care
Journal Of Aging And Health
American Journal Of Managed Care
Journal Of Interprofessional Care
Expert Review Of Pharmacoeconomics & Outcomes Research
Journal Of Behavioral Health Services & Research
Journal of Pediatric Health Care
BMC International Health and Human Rights
Health Care Management Review
Journal For Healthcare Quality
Journal Of Community Health
Health Communication
Health Care Management Science
Journal Of Health Politics Policy And Law
Qualitative Health Research
Journal Of Mental Health Policy And Economics
Disability And Health Journal

Journal Of Rural Health
Australian Journal of Primary Health
International Journal Of Health Planning And Management
Journal Of Healthcare Management
Community Mental Health Journal
Journal Of Health Care For The Poor And Underserved
Journal of Policy and Practice in Intellectual Disabilities
Quality Management In Health Care
Australian Health Review
International Journal Of Health Services
Inquiry-The Journal Of Health Care Organization Provision And Financing
International Journal of Health Economics and Management